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Briefings on How To Use the Federal Register—
For information on briefings in Denver, CO, see
announcement on the inside cover of this issue.

Federal Register



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THE FEDERAL REGISTER

WHAT IT IS AND HOW TO USE IT

- FOR:** Any person who uses the Federal Register and Code of Federal Regulations.
- WHO:** The Office of the Federal Register.
- WHAT:** Free public briefings (approximately 2 1/2 hours) to present:
1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
 2. The relationship between the Federal Register and Code of Federal Regulations.
 3. The important elements of typical Federal Register documents.
 4. An introduction to the finding aids of the FR/CFR system.
- WHY:** To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

DENVER, CO

- WHEN:** December 15; at 9 a.m.
- WHERE:** Room 239, Federal Building, 1961 Stout Street, Denver, CO.
- RESERVATIONS:** Call the Denver Federal Information Center, 303-844-6575

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Rules and Regulations

Federal Register

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 351

Reduction in Force

AGENCY: Office of Personnel Management.

ACTION: Final regulation.

SUMMARY: Consistent with a court order, OPM is issuing a revised regulation covering reduction in force appeals to the Merit Systems Protection Board (MSPB). The new amendment deletes a provision in current regulations that restricted hearings in reduction in force appeals before the Board.

EFFECTIVE DATE: This regulation becomes effective on December 4, 1987.

FOR FURTHER INFORMATION CONTACT: Thomas A. Glennon or Edward P. McHugh, (202) 632-6817.

SUPPLEMENTARY INFORMATION:

Discussion

Consistent with the decision of the United States Court of Appeals for the District of Columbia Circuit in *American Federation of Government Employees, AFL-CIO v. Office of Personnel Management*, 821 F.2d 761 (D.C. Cir. 1987), OPM is revising § 351.901 to delete language restricting the right to a hearing in a reduction in force appeal before the Merit Systems Protection Board.

Immediate Implementation of Change

I find that there is good reason to make this revision effective in less than 30 days (5 U.S.C. 553(d)(3)). The regulation is effective immediately because this change results from a court order rather than from a discretionary policy decision.

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the regulation applies only to Federal agencies.

List of Subjects in 5 CFR Part 351

Administrative practice and procedure, Government employees.

U.S. Office of Personnel Management.

James E. Colvard,
Deputy Director.

Accordingly, OPM amends 5 CFR Part 351 as follows:

PART 351—REDUCTION IN FORCE

1. The authority citation for Part 351 continues to read as follows:

Authority: 5 U.S.C. 1302, 3502; § 351.1005 is also issued under 5 U.S.C. 1315.

2. Section 351.901 is revised to read as follows:

§ 351.901 Appeals.

An employee who has been furloughed for more than 30 days, separated, or demoted by a reduction in force action may appeal to the Merit Systems Protection Board.

[FR Doc. 87-27847 Filed 12-3-87; 8:45 am]

BILLING CODE 6325-01-M

5 CFR Part 540

Performance Management and Recognition System; Minimum Performance Award Funding

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is revising the minimum percentage for calculating funds to pay performance awards to Performance Management and Recognition System (PMRS) employees for Fiscal Years 1988 and 1989. Establishing a new minimum percentage for each year is required by title II of the Civil Service Retirement Spouse Equity Act of 1984, which established the PMRS.

EFFECTIVE DATE: October 1, 1987.

FOR FURTHER INFORMATION CONTACT: Janice Smith, (202) 632-7630.

SUPPLEMENTARY INFORMATION: On August 4, 1987, at 52 FR 28840, OPM published a proposed regulation setting the minimum funding for performance awards to be paid to PMRS employees for Fiscal Years 1988 and 1989, with a 30-day comment period. During the comment period, which ended September 3, 1987, OPM received no agency comments on the proposed regulation.

Waiver of 30-Day Delay in Effective Date of Final Regulation

Pursuant to section 553(d)(3) of title 5 of the United States Code, I find that good cause exists to make this amendment effective in less than 30 days. The regulation is being made effective retroactively to meet the requirement in section 5406(c)(2)(A)(i) of title 5, U.S. Code, that OPM prescribe regulations annually adjusting the percentage incrementally over the previous fiscal year. October 1, 1987, begins a new Fiscal Year (FY 88) and therefore OPM must adjust the minimum percentage for performance awards incrementally over the minimum percentage used in Fiscal Year 1987 on that date.

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the regulations will only affect Government employees and agencies.

List of Subjects in 5 CFR Part 540

Government employees, Wages.

U.S. Office of Personnel Management.

Constance Horner,
Director.

Accordingly, OPM is amending 5 CFR Part 540 as follows:

PART 540—PERFORMANCE MANAGEMENT AND RECOGNITION SYSTEM

1. The authority citation for Part 540 continues to read as follows:

Authority: 5 U.S.C. Chapters 43 and 54.

2. In § 540.109, paragraphs (b)(1)(i) and (b)(1)(ii) are revised to read as follows:

§ 540.109 Performance awards.

* * * *

(b) * * *

(1) * * *

(i) Each agency is required to pay a minimum of 1.05 percent of the estimated aggregate amount of PMRS employees' basic pay for Fiscal Year 1988 for performance awards;

(ii) In accordance with chapter 54 of title 5 United States Code, the minimum percentage to be spent for performance awards will be 1.15 percent for Fiscal Year 1989.

* * * *

[FR Doc. 87-27848 Filed 12-3-87; 8:45 am]

BILLING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. 87-165]

Apples and Pears From Europe

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the Fruits and Vegetables regulations to relieve restrictions on the importation of apples or pears from certain European countries. Our rule will allow these fruits to be imported only under multiple safeguards, including inspections. These safeguards will ensure that the apples and pears can be imported with negligible risk of introducing insect pests into the United States.

EFFECTIVE DATE: December 2, 1987.

FOR FURTHER INFORMATION CONTACT: Frank Cooper, Staff Officer, Regulatory Services Staff, Plant Protection and Quarantine, APHIS, USDA, Room 637, Federal Building, Hyattsville, MD 20782; 301-436-8248.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR 319.56 (the regulations) prohibit or restrict the importation of certain fruits and vegetables into the United States because of the risk that the fruits or vegetables could introduce insect pests that could damage domestic plants.

In the Federal Register of October 14, 1987 (52 FR 38210-38215, Docket No. 87-

145), we proposed to amend the regulations by adding administrative instructions for importing apples from Belgium, Denmark, France, Great Britain, Italy, the Netherlands, Northern Ireland, Norway, Portugal, the Republic of Ireland, Sweden, Switzerland, and West Germany; and pears from Belgium, France, Great Britain, Italy, the Netherlands, Portugal, and Spain. The administrative instructions prescribed multiple safeguards, including inspections, to ensure that the fruits could be imported without significant risk of introducing insect pests, including the pear leaf blister moth (*Leucoptera malifoliella*; also referred to as *Leucoptera scitella*) into the United States.

We solicited comments on the proposed rule, stipulating that consideration would be given only to written comments postmarked or received on or before October 29, 1987.

We received 37 comments for consideration, 9 in favor and the remainder opposed. These comments were from growers, growers' associations, and other representatives of growers in the United States; members of Congress; importers; distributors; state departments of agriculture; a university entomologist; the French Government; and a representative of French apple producers and exporters.

All comments were carefully considered, and those which raised objections to the proposal are discussed in this supplementary information. Except as explained below, we have adopted the provisions of the proposed rule as a final rule for the reason set forth in the proposal and in this document.

Comments

A number of commenters asserted that our proposed inspection procedures for apples and pears are "inadequate," as shown by Dr. Barry Wilk in his report, "Evaluation of 'Establishment Threshold Levels' USDA Report." The commenters are referring to a report by Larry Orsak, Dr. Barry M. Wilk, and Dr. Clifford Kitayama, "Evaluation of 'Establishment Threshold Levels' USDA Report," which analyzes a U.S. Department of Agriculture document called "Establishment Threshold Levels." The report by Orsak, Wilk, and Kitayama was submitted by a grower as evidence that our proposed inspection procedures are inadequate. For clarity, we will refer to the Orsak, Wilk, and Kitayama report as the "Wilk Report," and to the "Establishment Threshold Levels" document as the "USDA document."

The USDA document analyzes the level of commodity infestation that could enter the United States with negligible risk of successful colonization. The document lists 28 factors that affect the probability of a pest becoming successfully established in a new territory. Applying these factors to what is known about the pear leaf blister moth, the document estimates the probability of the pest becoming established in the United States, based on various amounts of infested fruit entering the country. These probability estimates are contained in a table entitled, "Establishment Threshold Levels." This table indicates that if five cartons per 1,000 cartons of apples or pears are infested (a 0.5 percent level of infestation), and favorable conditions exist for establishment of the pest, the probability of an infestation occurring is 50 percent.

This statement is erroneous. The table, added to the USDA document after the rest of the document had been typed, was never proofed by the scientists who prepared the document. The table should have indicated that if five cartons per 1,000 cartons of apples or pears are infested (a 0.5 percent level of infestation), and favorable conditions exist for establishment of the pest, the probability of an infestation occurring is *less than 1 percent*. The next line of the table should have indicated that if 16 cartons per 1,000 are infested (a 1.6 percent level of infestation), and favorable conditions exist for establishment of the pest, the probability of an infestation occurring is 50 percent. This transcribing error was not discovered until we reviewed the comments on our proposal.

Not surprisingly, the Wilk Report's criticism of our proposed inspection procedures focuses on the erroneous information contained in the "Establishment Threshold Levels" table. The Wilk Report states: "... this USDA report projects that such a low infestation level—even less than 1%—has a 50% probability of leading to pest establishment in the U.S."

The probability projections on which this statement is based, when corrected as shown above, indicate a much lower probability of *Leucoptera* becoming established in the United States: less than 1 percent for a 0.5 percent level of infestation. A probability of 50 percent is projected only for infestation levels that reach 1.6 percent. Moreover, as explained in the USDA document, these projected probabilities are what might be expected if favorable conditions existed for establishment of the pest; in other words, these projected

probabilities represent a worst-case scenario. This concept is discussed in more detail later in this supplementary information.

The Wilk Report also evaluates the chances of detecting various hypothetical infestation levels (e.g., 1 percent, 2 percent, etc.) of *Leucoptera* if we inspected 2 percent of the cartons in any lot of apples and pears presented for shipment to the United States. Using a method called binomial approximation, the report calculates that a 2-percent inspection would fail to detect infestations at the 1 percent level (10 infested cartons per 1,000) 37 percent of the time. In other words, a 2-percent inspection would detect infestations at the 1 percent level with only 63 percent confidence. Based on this calculation, the Wilk Report then concludes: "On a statistical foundation alone (not even considering less than perfect inspections, or unintentionally biased inspections e.g., taking cases only from the top of a truck or pallet load), current inspection procedures have over a 35% probability of *not* detecting 1% *Leucoptera* infestation levels in incoming apples."

The Wilk report then applies this probability to our erroneous projection of a 50 percent probability of infestation in the United States if shipments infested at a 0.5 percent level are allowed to enter the United States and projects disaster: "If the USDA accepts the results of its own probability projections concerning the likelihood of *Leucoptera* becoming established—as detailed in the USDA report we examined—then there is no possible alternative to the conclusion that current inspection procedure is ineffective in preventing the eventual establishment of this pest in the United States when following the standard 'inspection' strategy for imported European apples."

In fact, our proposed inspection procedure is not a percentage inspection procedure, 2 percent or otherwise. Rather, it is a biometrically designed statistical sampling procedure that results in a higher probability of detecting infestations than the 2-percent inspection procedure. Because the procedure involves selection of a biometrically designed statistical sample, it prevents the "unintentionally biased inspections" mentioned in the Wilk Report.

By way of illustrating the differences between the 2-percent inspection procedure referred to in the Wilk report and the procedure we proposed, a 2-percent inspection of a lot of 1,000 cartons would involve examination of only 20 cartons in the lot. We estimate that this type of inspection could result

in detection of infestations at or above the 14 percent level (140 infested cartons per 1,000). (In discussing infestation levels, we mean the percent of cartons in the lot presented for inspection that contain one or more *Leucoptera*.) For the same sized lot of 1,000 cartons, our biometrically designed inspection procedure would involve inspection of 250 cartons, and would lead to detection of 1 percent levels of infestation (10 infested cartons per 1,000) with close to 95 percent confidence. This level of infestation is well below the 1.6 percent level that our corrected "Establishment Level Threshold" table indicates could result in a 50 percent probability of successful colonization of *Leucoptera* in the United States.

Note that the preceding sentence says *could* result in a 50 percent probability of successful colonization. As mentioned above, the probabilities projected in the "Establishment Threshold Levels" table represent what might be expected if favorable conditions existed for establishment of the pest. This qualification is clearly stated in the preamble to the USDA document. This preamble states, in part, "In attempting to establish the level of infestation that can be tolerated without significant risk of successful establishment of a viable population of a pest species, it is necessary to examine the question in terms of a worst case context, i.e., that a critical number of a specified organism will arrive at an ecologically favorable site."

Many factors would affect the chances of a critical number of *Leucoptera* arriving at an ecologically favorable site. First, our proposed inspection protocol would ensure a very high probability that infested lots would be detected and rejected. Although it is possible that very low levels of infestation could remain undetected, it is unlikely that these low levels would result in a sufficient number of live *Leucoptera* arriving at an ecologically favorable site in the United States.

Once in the United States, shipments of European apples and pears would normally be broken down at the port of arrival into truckloads of no more than approximately 1,000 cartons each. Each truckload would then be moved directly to a market, or to a warehouse for subsequent delivery to a market, and from there to consumers. Any infested fruit in the shipment would, therefore, be dispersed, decreasing the potential number of *Leucoptera* in any one place. As explained in more detail below, the smaller the number of *Leucoptera*, the poorer the chances of colonization.

The distribution chain also would reduce opportunities for any *Leucoptera*

that might be present on the apples or pears to come into contact with a host plant, without which *Leucoptera* cannot colonize. Any *Leucoptera* that might be present on the apples or pears would normally be in the pupal (cocoon) stage, since that is the life stage that attaches to fruit. Therefore, European apples and pears would come into contact with host plants only if consumers placed the fruit in a field or orchard where host plants existed, or if fruit being trucked to market were deposited in a field or orchard where host plants existed. Although it is possible that some consumers might toss a European apple or pear into such an orchard or field, very little of this fruit is likely to be disposed of this way. Any fruit that might be disposed of in this manner would probably not be carrying enough live *Leucoptera* to cause an infestation. Other factors also would greatly reduce the likelihood of European apples or pears causing an infestation of *Leucoptera*. (The chances of a small number of *Leucoptera* colonizing successfully are discussed in more detail below.) It is also possible that a truck carrying the fruit to market could be involved in an accident, but the likelihood is low. The likelihood is lower still that the accident would occur near host plants, that the accident would cause the fruit to be spilled from the truck, and that the spilled fruit would be abandoned.

Nonetheless, even a truckload of fruit abandoned near host plants would not present a significant risk of causing an infestation. Based on our proposed inspection protocol (discussed in more detail later), we estimate that fewer than 10 cartons per 1,000 that cleared inspection procedures would contain any *Leucoptera*. As already mentioned, any *Leucoptera* that might be present would be in the pupal stage. However, the presence of cocoons would not necessarily indicate live *Leucoptera* pupae. We know, for example, that French growers apply chemical treatments in their orchards if needed for insect pests. Some *Leucoptera* larvae treated in this manner would suffer from acute toxicity and die immediately. Others would not survive to reproduce. For example, the larvae might pupate but die before the adults could emerge from the cocoon. Parasitism of *Leucoptera* also has been recorded at from 10 to 90 percent, and this would kill some pupae. Some *Leucoptera* also would die from natural causes, such as insufficient nutrition or physical defects, and others would have been injured during picking, hauling, packing, and inspection of the fruit.

The continued survival of any remaining pupae also would not be assured. For example, pupae arriving in the fall in cooler areas of the United States would have to overwinter. Normal pupal mortality under winter conditions alone would minimize the possibility that enough *Leucoptera* would survive to start a colony. Other factors, such as animals eating the abandoned fruit, would affect the pupae in any geographical area, and would also reduce the number of *Leucoptera* likely to survive.

Moths that emerge from their cocoons would be able to reproduce only if all of the following conditions are met: (1) The emergent moths must include both males and females; (2) they must be healthy and fertile; (3) they must find each other and mate within a certain amount of time (mating occurs within 50 to 60 hours after the moths emerge, and the moths themselves do not live long—5 days for males and 8–10 days for females; distance of the moths from each other also would be a factor in their mating success, since adult moths can fly only 4–5 meters); and (4) the mated females must find a suitable host plant on which to lay their eggs. Female moths lay their eggs on leaves of host plants, and the leaves serve as the food source for any resulting larvae. If the females cannot reach a suitable host plant, or if leaves on a host plant are unavailable—for example, because of mining by some other insect or because they are senescent—then the eggs or larvae will not develop further. Development of eggs and larvae also require temperatures of 27–28 °C over a period of about 3 weeks. If even one part of this reproduction process were unsuccessful, the *Leucoptera* could not colonize.

We therefore believe that, given our inspection protocol, the likelihood of sufficient numbers of live *Leucoptera* arriving at an ecologically favorable site is so low as to make the risk of their establishment negligible.

Most of the commenters who cited the Wilk report as evidence that our proposed inspection procedures were "inadequate" also stated that this "inadequacy" was "verified and strengthened by Dr. Harrison Stubbs and Dr. Stanley Hoyt." Drs. Stubbs and Hoyt commented separately on the proposed rule. Dr. Stubbs, who identified himself as a biostatistical consultant, provided a statistical analysis of our protocol for inspecting European apples and pears. Dr. Hoyt, who identified himself as an entomologist at Washington State University's Tree-Fruit Research Center,

based his comments on the conclusions in the Wilk report and the Stubbs letter.

Dr. Stubbs' letter includes the calculations in the Wilk report concerning the chances of detecting various hypothetical infestation levels (e.g., 1 percent, 2 percent, etc.) of *Leucoptera* if 2 percent of the cartons presented for exportation to the United States were inspected. As we stated earlier, our inspection protocol is not a 2-percent sampling procedure.

Dr. Stubbs also evaluates the probabilities of detecting various hypothetical infestation levels with our proposed inspection protocol. He makes the following assumptions: (1) 250 bins sampled; (2) an equal probability of infestation for each bin; (3) various infestation levels. He then projects "probabilities of no detection" for the following "infestation rates":

Infestation rate (percent)	Probability of no detection (percent)
0.1	78
0.2	61
0.3	47
0.4	37
0.5	29
1.0	8
2.0	8

Dr. Stubbs then concludes: "The results indicate that the pear leaf blister moth has an unacceptably high probability of escaping detection under the proposed inspection procedures."

Dr. Stubbs' chart, above, apparently is based on inspection of 250 cartons (not bins, as stated by Dr. Stubbs) in a lot of 100,000 cartons. Although it is possible that lots this large would be presented for inspection, most lots probably would be between 12,000 and 15,000 cartons. Nevertheless, even for lots of 100,000, Dr. Stubbs' chart shows that our proposed inspection protocol would detect infestations at the 1.0 percent level (10 infested cartons per 1,000) with 92 percent confidence. As we have already discussed, infestations at levels low enough to miss detection would not lead to a significant risk of *Leucoptera* becoming established in the United States.

After reviewing Dr. Stubbs' analysis, however, we have decided to increase the number of cartons we will examine in each lot presented for inspection (called an "inspection unit" in the proposal and final rule) from 250 to 300. Although we believe inspection of 250 cartons is more than adequate for most lots that would be presented for inspection, 300 cartons would provide additional security for very large lots.

Examination of a biometrically designed statistical sample of 300 cartons drawn from each inspectional unit will result in detection of infestations at the 1.0 percent level (10 infested cartons per 1,000) with better than 95 percent confidence, even for lots as large as 100,000 cartons.

Dr. Hoyt states: "[The Wilk report and the Stubbs letter] raise a valid concern as to whether the inspection procedure can prevent the entry and establishment of *Leucoptera scitella* in the United States. I am an entomologist rather than a statistician so I feel compelled to accept the analyses presented. Assuming the evaluation of the inspection levels and infestation levels is correct, the question which arises is whether the goal is to prevent establishment of the species in the United States. If this is the goal, it seems clear that other methods (treatment, quarantine) are essential to protect the American fruit industry." Dr. Hoyt also states that procedures used should ensure that *Leucoptera* is "prevented from establishing in the U.S., not just reduce the likelihood of establishment."

As Dr. Hoyt points out, his comments are based on the assumption that the Wilk and Stubbs evaluations of inspections and infestation levels are correct. We have already explained that they are not, and that our inspection protocol, especially as we have strengthened it, will result in a negligible risk of *Leucoptera* becoming established in the United States. Dr. Hoyt's comment that other methods, such as treatment or quarantine, should be required to prevent the introduction of *Leucoptera* are discussed below, since similar comments were made by others.

Two commenters, including Dr. Hoyt, objected to our relying on an inspection protocol and recommended that we require treatment or quarantine of European apples and pears. Three other commenters maintained that we should institute some type of treatment of fumigation process. And another four commenters specified that the proposed inspection protocol should be replaced with a requirement that the apples and pears be treated by fumigation. No changes have been made based on these comments.

If, by "quarantine," the commenters mean a total ban on shipments of European apples and pears to the United States, we have already shown that this extreme measure is not necessary. Prohibition of the fruit would only be indicated if we had no way of ensuring that the fruit would present an insignificant risk of introducing insect

pests. Our inspection protocol will ensure that this risk is negligible.

If, by "quarantine," the commenters mean holding the fruit temporarily to see if insects emerge, then quarantine is neither practicable nor necessary. Holding the fruit at temperatures warm enough for *Leucoptera* pupae to develop would encourage spoilage of the fruit; holding the fruit under refrigeration would prolong the inactive stage of the insect and reveal nothing.

Treatments, including fumigation, are generally ineffective against the pupal stage of *Leucoptera*, which, as we have explained, is the life stage of the insect that could be attached to the apples or pears. Therefore, little would be gained by requiring treatment in addition to our protocol, and much could be lost if our inspection protocol were replaced by a requirement that the apples and pears be fumigated.

Again, European apples and pears imported in accordance with our protocol will present a negligible risk of introducing *Leucoptera*. Under these circumstances, additional treatments, including quarantine or fumigation, are unnecessary.

Two commenters who supported our proposed rule requested a change to a proposed packing shed procedure. Under § 319.56-2r(c)(3)(iii), if any apples or pears inspected at a packing shed are found to contain any live *Leucoptera*, the entire grower lot must be rejected for shipment to the United States. However, if any insect pest is found for which a treatment authorized in the Plant Protection and Quarantine Treatment Manual (PPQ Treatment Manual) is available, the apples or pears would remain eligible for shipment to the United States only if the entire grower lot is treated for the pest under the supervision of a Plant Protection and Quarantine (PPQ) inspector. The commenters asked that "an official of the plant protection service of the exporting country" be responsible for supervising any treatment of the apples or pears in the packing shed. No changes have been made based on these comments.

It is our policy to require a PPQ inspector to supervise treatments when the treatments are a condition of importation. This is necessary to ensure that the treated fruit meets our standards for importation. The requirement is contained in § 319.56-2(e), which provides, among other things, that fruits or vegetables may be imported if "they have been treated, or are to be treated, in accordance with such conditions and procedure as may be prescribed by the Deputy Administrator of the Plant Protection

and Quarantine Programs, under the supervision of a plant quarantine inspector of the said Department."

Nine commenters raised objections to the proposed rule because of past problems associated with preclearance of apples and pears from France. Those commenters who cited specific problems referred to the failure of the French fruit industry to comply with preclearance procedures for the 1986 crop, which resulted in the United States imposing a temporary embargo on shipments of apples or pears from France. No changes have been made based on these comments.

We have in the past rejected shipments of French apples and pears because of *Leucoptera* and other insect pests. In 1986, we terminated a preclearance program with the French fruit industry because too many lots presented for inspection had to be rejected because of insect pests, including *Leucoptera*, and because we found evidence that a previously rejected lot was presented for inspection a second time, in violation of preclearance procedures.

Our termination of the preclearance program for French apples and pears in 1986 sent a clear message that (1) we expect fruit presented for shipment to the United States to meet our standards for importation; and (2) we will not tolerate violations of our protocol.

To avoid a repetition of the problems we encountered in 1986, we have clarified the rule to stipulate that European apples and pears may be imported during a given shipping season only if certain conditions are met in the exporting country for that shipping season. Moreover, we have added a statement that failure to comply with these conditions may be cause for terminating the preclearance program by the Administrator. These conditions will reduce the likelihood that any apples or pears presented for shipment to the United States will contain any insect pests, including *Leucoptera*. They include, but are not limited to, (1) surveying orchards for evidence of any leaf mines that suggest the presence of *Leucoptera*; (2) rejecting fruit from any orchard where there are leaf mines suggesting the presence of *Leucoptera*; (3) monitoring application of pesticides in orchards, when pesticides are required by our regulations; and (4) inspecting a certain amount of fruit from each grower lot in packing sheds. The rule also prohibits any apples or pears rejected for shipment to the United States from being presented for shipment a second time.

Our rule also provides that if inspections at the packing shed reveal

any live larva or pupa of *Leucoptera*, then the entire grower lot must be rejected for shipment to the United States and the plant protection service must reject for shipment any additional fruit from the producing orchard for the remainder of that shipping season. If any other insect pests referred to in the rule are found in a grower lot at a packing shed, and a treatment authorized in the PPQ Treatment Manual is available, the fruit will remain eligible for shipment to the United States only if the entire grower lot is treated under the supervision of a PPQ inspector. However, if the entire grower lot is not treated in this manner, or if a pest is found for which no authorized treatment is available, the entire grower lot must be rejected for shipment to the United States.

Under the terms for preclearance inspections, if PPQ inspectors find any live larva or pupa of *Leucoptera*, the inspection unit (lot presented for inspection) must be rejected for shipment to the United States. The inspectors also will reject any additional fruit from the producing orchard for the remainder of the shipping season. Furthermore, if inspectors reject any three inspection units in a single season because of *Leucoptera* on fruit processed by a single packing shed, no additional fruit from that packing shed will be accepted for shipment to the United States for the remainder of that shipping season. In the case of other insect pests referred to in the rule, if a treatment authorized in the PPQ Treatment Manual is available, the fruit will remain eligible for shipment to the United States only if the entire inspection unit is treated under the supervision of a PPQ inspector. However, if the entire inspection unit is not treated in this manner, or if a pest is found for which no authorized treatment is available, the entire inspection unit must be rejected for shipment to the United States.

The rule also contains provisions for terminating a preclearance program with a country if PPQ inspectors repeatedly have to reject inspection units because of insect pests. The conditions under which we would terminate a preclearance program because of repeated findings of *Leucoptera* are contained in § 319.56-2r(e)(1); the conditions under which we would terminate a preclearance program because of repeated findings of other pests are contained in § 319.56-2r(e)(2).

With these penalties, which include termination of the preclearance program if necessary, we believe that both the fruit industries and plant protection

services of any exporting country will be highly motivated to comply with the requirements in our rule.

Two commenters maintained that France and other European countries have had problems controlling *Leucoptera* and expressed concern about the difficulties and costs that growers in the United States could face if the pest became established here. Four commenters asserted that we should not adopt the proposed rule until an effective treatment or eradication program is developed for *Leucoptera*. No changes have been made based on these comments.

In France and other European countries where *Leucoptera* is fairly widespread, an eradication program is not practicable. The insect is controlled, however, by both pesticides and naturally occurring parasites. In the United States, any introduction of *Leucoptera* would be taken very seriously, and PPQ would take immediate action to contain and destroy the pest. Although a specific action plan has not been prepared, many of the tools that could be used, such as our Preparedness for Emergency Pest Action cadre (a team of specialists), are already in place in case of any plant pest emergency. A specific action plan for *Leucoptera* could be assembled quickly based on available knowledge of the insect, including European data and experiences on the biology of the insect and procedures for survey and control. We also would look to ongoing research, such as on the development of pheromones, for new approaches. Once again, however, we must emphasize that the risk of *Leucoptera* becoming established in the United States because of European apples or pears imported under our rule is extremely low. Therefore, we do not anticipate that growers in the United States will be confronted with costs or other burdens related to controlling *Leucoptera*.

One commenter questioned the level of protection offered by our inspection protocol, stating: "Rather than meeting the generally accepted standard of Probit-9, the protocol would provide at best a 95% level of confidence that the U.S. would not be exposed to infestation of the pear leaf blister moth." No changes have been made based on this comment.

Probit-9 is a generally accepted standard for effectiveness of treatments, such as cold treatment or fumigation. It is a statistical statement of the level of control the treatments provide, and is based on experiments confirming the level of treatment required to kill a particular pest. However, Probit-9 is not the standard for inspection protocols.

The commenter also has misstated what the "95% confidence level" indicates. Our inspection protocol will ensure detection of infestations at the 1 percent level (10 infested cartons per 1,000) with 95 percent confidence. For reasons we discussed earlier, infestations at levels low enough to miss detection would present a negligible risk of *Leucoptera* becoming established in the United States.

Two commenters asserted that our rule should include precautions to assure protection from plant diseases. They specifically mentioned the following three plant pathogens that do not occur in the United States: *Monilinia fructigena*, *Ascochyta pirina*, and *Phacidiophsia malorum*. No changes have been made based on these comments.

Of the three plant pathogens specified by the commenters, *Ascochyta pirina* and *Phacidiophsia malorum* are mainly foliage pathogens. They are not known to attack fruit. *Monilinia fructigena* is a brown rot of fruit. It is easily observable on fruit when present, and, therefore, would lower the value of any fruit sent to market. Therefore, most apples or pears with the disease never leave the orchard, and any that are missed at that stage are culled out during normal packing shed operations. PPQ inspectors also look for evidence of diseases on plant products presented for importation, and would reject any European apples or pears that showed symptoms of *Monilinia fructigena*.

We do not refer to plant diseases in our rule because the rule is part of a quarantine that applies specifically to insect pests. Other regulations prohibit or restrict the importation of various plant products because of certain other pests and diseases. In addition, section 105 of the Federal Plant Pest Act (7 U.S.C. 150ee) provides, among other things, that the Secretary of Agriculture may take emergency measures to prevent the dissemination of any plant pest, including pathogens, that are new to or not widely distributed in the United States.

Two commenters asserted that our preclearance protocol is unworkable because the number of countries covered would stretch PPQ's manpower and budgetary resources beyond its capability. No changes have been made based on these comments.

First of all, the rule provides that European apples and pears will be eligible for preclearance inspection in the exporting country only if the national plant protection service of that country has entered into a trust fund agreement with PPQ for that shipping season. This agreement requires the

plant protection service to pay in advance all costs that PPQ estimates it will incur in providing the preclearance inspections. These costs will include administrative expenses incurred in conducting the inspections; all salaries (including overtime and the federal share of employee benefits); travel expenses (including per diem expenses); and all other incidental expenses incurred by the inspectors in performing these services. Therefore, performing preclearance inspections will not be a financial burden on PPQ.

With regard to available manpower, inspectors would be required whether we inspect the fruit in the exporting country or in the United States. In fact, preclearance may be a more efficient use of manpower than inspection in the United States. The latter, which § 319.56-2r(h) of our rule allows for under certain circumstances, places additional responsibilities on inspectors and, therefore, may require more inspectors than preclearance in the exporting country. These additional responsibilities include (1) ensuring that each pallet of apples or pears is completely enclosed in plastic, before it is offloaded, to prevent the escape of insects; and (2) supervising the offloading of the entire shipment of apples or pears and the movement of the shipment to an enclosed warehouse.

Also, if multiple European countries did enter into agreements with PPQ for preclearance of apple or pears, inspectors could travel from one country to the next to perform the work. The countries eligible for this program are all reasonably close to one another, and all the fruit would not be ready for inspection at the exact same time. In any event, the availability of inspectors is one of the factors PPQ would consider before entering into any agreement for preclearance of European apples and pears. If, for any reason, PPQ anticipated that sufficient inspectors would not be available, it would not enter into the agreement.

Two commenters requested that an APHIS official sign every phytosanitary certificate accompanying the apples or pears. No changes have been made based on these comments.

Phytosanitary certificates are internationally recognized documents issued by most exporting countries of the world to certify that officials of the exporting country have inspected the commodity to be shipped and believe it to be free of injurious plant pests and diseases. Under the Plant Quarantine Act (7 U.S.C. 151 *et seq.*), this certificate must be "from the proper official of the country from which the importation is

made." This requirement places the burden of providing acceptable exports on officials of an exporting country. Therefore, APHIS officials cannot sign a phytosanitary certificate for any foreign commodity, including apples or pears from Europe.

In any case, an APHIS signature on these certificates is unnecessary because we will not rely on phytosanitary certificates to ensure that any apples or pears qualify for importation. Our rule provides that acceptance or rejection of any shipment of apples or pears must be based on PPQ inspection of the fruit. Apples or pears that pass our preclearance inspection will be accompanied to the United States by a PPQ Form 203, "Foreign Site Certificate of Preclearance," and this form is signed by an APHIS official.

One commenter suggested that we require "mandatory APHIS involvement in orchard selection and inspection of packing sheds." No changes have been made based on this comment.

We believe that orchard selection and packing shed inspections are properly the responsibility of the national plant protection service and the fruit industry of an exporting country, and that our role should be one of oversight and review. Orchard selection and packing shed inspections are for the purpose of ensuring that apples and pears presented for PPQ inspection are of a phytosanitary quality that will make our preclearance program operationally practical. The PPQ inspection, however, is the point at which the apples or pears are determined to be admissible into the United States. To reiterate a point we made earlier, our rule does contain strong incentives for the national plant protection service and the fruit industry of an exporting country to comply with our protocol for orchard selection and packing shed inspections. Rejections of apples or pears because of *Leucoptera* will result in rejection of any additional fruit from the producing orchard and may result in rejection of additional fruit from the packing shed that processed the infested fruit. Finally, if the rejection rate of apples or pears because of *Leucoptera* or other insect pests exceeds the levels specified in § 319.56-2r(h) of our rule, the preclearance program will be terminated.

Two commenters asserted that we should require labeling and lot stamping of each carton of apples or pears presented for shipment to the United States. No changes have been made based on these comments.

The rule requires each carton of apples or pears presented for inspection to be identified with the packing shed

where they were processed, as well as with the producing orchard. This identification requirement is sufficient to enable PPQ to trace the fruit should it be found infested.

The commenters apparently wish each carton to be stamped in a manner that would identify it with the lot in which it is presented for preclearance inspection ("inspection units"). Inspection units consist of a minimum of 6,000 cartons, usually from more than one packing shed. The particular cartons that make up an inspection unit are selected after the cartons arrive at the location where PPQ inspection will take place. This is usually the point from which qualified inspection units will be shipped to the United States. Because each inspection unit consists of a minimum of 6,000 cartons, it is not operationally practical for each carton to be stamped at the time of inspection in a manner that would identify it with its inspection unit. Furthermore, because each inspection unit usually includes cartons from more than one packing shed, cartons cannot be identified by inspection unit at the packing shed.

PPQ's system for selecting inspection lots and for controlling their disposition (passed or rejected) after inspection involves documentation of which cartons are in each lot, physical segregation of those cartons from others, and on-site monitoring. We consider this system to be acceptable for purposes of preventing the introduction of unapproved products and for preventing the reintroduction of previously rejected products. Violations of preclearance procedures would be cause for terminating the preclearance program.

One commenter suggested mandatory reinspection of European apples and pears upon the arrival of the fruit in the United States and spot checks of the fruit at ports of arrival after the first year. No changes have been made based on this comment.

Because preclearance inspections are performed by PPQ inspectors, we do not believe it is necessary to require mandatory reinspection or spot checks of the apples or pears. However, inspectors on duty at ports of arrival are responsible for checking each shipment that arrives in the United States to ensure that the accompanying paperwork is in order and that the product presented for importation appears to be the product identified in the paperwork. If they find any evidence of misrepresentation or adulteration of the product, they have the right and the obligation to inspect the product to determine whether it meets our requirements for importation.

Miscellaneous

Our proposed rule required the plant protection service of an exporting country to enter into a cooperative agreement with PPQ. This cooperative agreement required the plant protection service to agree that certain conditions for importation of apples and pears would be met before the fruit was presented for shipment to the United States. These conditions, set forth in § 319.56-2r(c), concern procedures related to orchard selection and packing shed inspections. Upon further consideration, we have determined that a cooperative agreement is not necessary to ensure these conditions are met. If the required conditions are not met, the preclearance program in a country may be terminated by the Administrator.

We have replaced the term "Deputy Administrator" wherever it appeared in the proposal with the term "Administrator" to reflect internal agency policy and have made minor, editorial changes for clarity.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than \$100 million; will not cause a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Based on interest expressed in importing apples from Europe, we anticipate that approximately 15 million pounds of apples will be imported from France during fiscal year 1988. We expect no apples from other countries covered by this rule and no pears. Apple production in the United States is estimated at approximately 8 billion pounds per year. Although there are probably many small business entities in the United States that grow, pack, or sell apples, we do not believe this rule will have a significant economic impact on them because the volume of French apples expected to be imported is relatively low and the French apples would compete equally in the market.

place with U.S.-produced apples. We believe that importers of French apples also import a variety of other fruits and vegetables and that importations of the French apples would constitute a small portion of their total importations.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with state and local officials. (See 7 CFR Part 3015, Subpart V.)

Paperwork Reduction Act

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Effective Date

The Administrator, Animal and Plant Health Inspection Service, has determined that this rulemaking proceeding should be expedited by making it effective upon signature. Importers in the United States have expressed interest in importing apples from France this season, and the shipping season for those apples has already begun. Meanwhile, exporters in France must quickly determine where their fruit will be marketed. Delaying the effective date of this rule could cause substantial economic losses for importers.

List of Subjects in 7 CFR Part 319

Agricultural commodities, Fruit, Imports, Plant diseases, Plant pests, Plants (agriculture), Quarantine, Transportation.

PART 319—FOREIGN QUARANTINE NOTICES

Accordingly, we are amending 7 CFR Part 319 as follows:

1. The authority citation for Part 319 continues to read as follows:

Authority: 7 U.S.C. 150dd, 150ee, 150ff, 151-167; 7 CFR 2.17, 1.51, and 371.2(c).

2. A new § 319.56-2r is added to read as follows:

§ 319.56-2r Administrative instructions governing the entry of apples and pears from certain countries in Europe.

(a) *Importations allowed.* Pursuant to § 319.56(c), the Administrator has determined that the following fruits may be imported into the United States in accordance with this subsection and other applicable provisions of this subpart:

(1) Apples from Belgium, Denmark, France, Great Britain, Italy, The Netherlands, Northern Ireland, Norway, Portugal, the Republic of Ireland, Sweden, Switzerland, and West Germany;

(2) Pears from Belgium, France, Great Britain, Italy, The Netherlands, Portugal, and Spain.

(b) *Trust fund agreement.* Except as provided in paragraph (h) of this section, the apples or pears may be imported only if the national plant protection service of the exporting country (referred to in this subsection as the plant protection service) has entered into a trust fund agreement with Plant Protection and Quarantine (PPQ) for that shipping season. This agreement requires the plant protection service to pay in advance all estimated costs incurred by PPQ in providing the preclearance inspections prescribed in paragraph (d) of this section. These costs will include administrative expenses incurred in conducting the inspection services; and all salaries (including overtime and the federal share of employee benefits), travel expenses (including per diem expenses), and other incidental expenses incurred by the inspectors in performing these services. The agreement requires the plant protection service to deposit a certified or cashier's check with the Animal and Plant Health Inspection Service (APHIS) for the amount of these costs, as estimated by PPQ. If the deposit is not sufficient to meet all costs incurred by PPQ, the agreement further requires the plant protection service to deposit with APHIS a certified or cashier's check for the amount of the remaining costs, as determined by PPQ, before the inspection will be completed.

(c) *Responsibilities of the exporting country.* The apples or pears may be imported in any single shipping season only if all of the following conditions are met:

(1) Officials of the plant protection service must survey each orchard producing apples or pears for shipment to the United States at least two times between the time of spring blossoming and harvest. If the officials find any leaf mines that suggest the presence of *Leucoptera malifoliella* in an orchard, the officials must reject any fruit

harvested from that orchard during that growing season for shipment to the United States. If the officials find evidence in an orchard of any other plant pest referred to in paragraph (g) of this section, they must ensure that the orchard and all other orchards within 1 kilometer of that orchard will be treated for that pest with a pesticide approved by the United States Environmental Protection Agency, in accordance with label directions and under the direction of the plant protection service. If the officials determine that the treatment program has not been applied as required or is not controlling the plant pest in the orchard, they must reject any fruit harvested from that orchard during that growing season for shipment to the United States.

(2) The apples or pears must be identified with the orchard from which they are harvested (the producing orchard) until the fruit arrives in the United States.

(3) The apples or pears must be processed and inspected in the approved packing sheds as follows:

(i) Upon arrival at the packing shed, the apples or pears must be inspected for insect pests as follows: For each grower lot (all fruit delivered for processing from a single orchard at a given time), packing shed technicians must examine all fruit in one carton on every third pallet (there are approximately 42 cartons to a pallet), or at least 80 apples or pears in every third bin (if the fruit is not in cartons on pallets). If they find any live larva or pupa of *Leucoptera malifoliella*, they must reject the entire grower lot for shipment to the United States, and the plant protection service must reject for shipment any additional fruit from the producing orchard for the remainder of the shipping season.

(ii) The apples or pears must be sorted, sized, packed, and otherwise handled in the packing sheds on grading and packing lines used solely for fruit intended for shipment to the United States, or, if on grading and packing lines used previously for other fruit, only after the lines have been washed with water.

(iii) During packing operations, apples and pears must be inspected for insect pests as follows: All fruit in each grower lot must be inspected at each of two inspection stations on the packing line by packing shed technicians. In addition, one carton from every pallet in each grower lot must be inspected by officials of the plant protection service. If the inspections reveal any live larva or pupa of *Leucoptera malifoliella*, the entire grower lot must be rejected for

shipment to the United States, and the plant protection service must reject for shipment any additional fruit from the producing orchard for the remainder of that shipping season. If the inspections reveal any other insect pest referred to in paragraph (g) of this section, and a treatment authorized in the Plant Protection and Quarantine Treatment Manual is available, the fruit will remain eligible for shipment to the United States if the entire grower lot is treated for the pest under the supervision of a PPQ inspector. However, if the entire grower lot is not treated in this manner, or if a plant pest is found for which no treatment authorized in the Plant Protection and Quarantine Treatment Manual is available, the entire grower lot will be rejected for shipment to the United States.

(4) Apples or pears that pass inspection at approved packing sheds must be presented to PPQ inspectors for preclearance inspection as prescribed in paragraph (d) of this section or for inspection in the United States as prescribed in paragraph (h) of this section.

(5) Apples and pears presented for preclearance inspection must be identified with the packing shed where they were processed, as well as with the producing orchard, and this identity must be maintained until the apples or pears arrive in the United States.

(6) Facilities for the preclearance inspections prescribed in paragraph (d) of this section must be provided in the exporting country at a site acceptable to PPQ.

(7) Any apples or pears rejected for shipment into the United States may not, under any circumstance, be presented again for shipment to the United States.

(d) *Preclearance inspection.* Preclearance inspection will be conducted in the exporting country by PPQ inspectors. Preclearance inspection will be conducted for a minimum of 6,000 cartons of apples or pears, which may represent multiple grower lots from different packing sheds. The cartons examined during any given preclearance inspection will be known as an inspection unit. Apples or pears in any inspection unit may be shipped to the United States only if the inspection unit passes inspection as follows:

(1) Inspectors will examine, fruit by fruit, a biometrically designed statistical sample of 300 cartons drawn from each inspection unit.

(i) If inspectors find any live larva or pupa of *Leucoptera malifoliella*, they will reject the entire inspection unit for shipment to the United States. The inspectors also will reject for shipment

any additional fruit from the producing orchard for the remainder of the shipping season. However, other orchards represented in the rejected inspection unit will not be affected for the remainder of the shipping season because of that rejection. Additionally, if inspectors reject any three inspection units in a single shipping season because of *Leucoptera malifoliella* on fruit processed by a single packing shed, no additional fruit from that packing shed will be accepted for shipment to the United States for the remainder of that shipping season.

(ii) If the inspectors find evidence of any other plant pest referred to in paragraph (g) of this section, and a treatment authorized in the Plant Protection and Quarantine Treatment Manual is available, fruit in the inspection unit will remain eligible for shipment to the United States if the entire inspection unit is treated for the pest under the supervision of a PPQ inspector. However, if the entire inspection unit is not treated in this manner, or if a plant pest is found for which no treatment authorized in the Plant Protection and Quarantine Treatment Manual is available, the inspectors will reject the entire inspection unit for shipment to the United States. Rejection of an inspection unit because of pests other than *Leucoptera malifoliella* will not be cause for rejecting additional fruit from an orchard or packing shed.

(iii) Apples and pears precleared for shipment to the United States as prescribed in this paragraph will not be inspected again in the United States (except as necessary to ensure that the fruit has been precleared) unless the preclearance program with the exporting country is terminated in accordance with paragraph (e) of this section. If the preclearance program is terminated with any country, precleared fruit in transit to the United States at the time of termination will be spot-checked by PPQ inspectors upon arrival in the United States for evidence of plant pests referred to in paragraph (g) of this section. If any live larva or pupa of *Leucoptera malifoliella* is found in any carton of fruit, inspectors will reject that carton and all other cartons in that shipment that are from the same producing orchard. In addition, the remaining cartons of fruit in that shipment will be reinspected as an inspection unit in accordance with the preclearance procedures prescribed in paragraph (d) of this section.

(e) *Termination of preclearance programs.* The Administrator may terminate the preclearance program in a country if he determines that any of the

conditions specified in paragraph (c) of this section are not met or because of pests found during preclearance inspections. Termination of the preclearance program will stop shipments of apples or pears from that country for the remainder of that shipping season. Termination of the preclearance program for findings of *Leucoptera malifoliella* in preclearance inspections in any country will be based on rates of rejection of inspection units as follows:

(1) Termination because of findings of *Leucoptera malifoliella*. The preclearance program will be terminated with a country when, in one shipping season, inspection units are rejected because of *Leucoptera malifoliella* as follows:

(i) 5 inspection units in sequence among inspection units 1-20, or a total of 8 or more of the inspection units 1-20;

(ii) 5 inspection units in sequence among inspection units 21-40, or a total of 10 or more of the inspection units 1-40;

(iii) 5 inspection units in sequence among inspection units 41-60, or a total of 12 or more of the inspection units 1-60;

(iv) 5 inspection units in sequence among inspection units 61-80, or a total of 14 or more of the inspection units 1-80;

(v) 5 inspection units in sequence among inspection units 81-100, or a total of 16 or more of the inspection units 1-100;

(vi) 5 inspection units in sequence among inspection units 101-120, or a total of 18 or more of the inspection units 1-120.

(Sequence can be continued in increments of 20 inspection units by increasing the number of rejected inspection units by 2.)

(2) Termination because of findings of other plant pests. The preclearance program will be terminated with a country when, in one shipping season, inspection units are rejected because of other insect pests as follows:

(i) 10 or more of the inspection units 1-20;

(ii) 15 or more of the inspection units 1-40;

(iii) 20 or more of the inspection units 1-60;

(iv) 25 or more of the inspection units 1-80;

(v) 30 or more of the inspection units 1-100; or

(vi) 35 or more of the inspection units 1-120.

(Sequence can be continued in increments of 20 inspection units by

increasing the number of rejected inspection units by 5.)

(f) *Cold treatment.* In addition to all other requirements of this section, apples or pears may be imported into the United States from France, Italy, Portugal, or Spain only if the fruit is cold treated for the Mediterranean fruit fly in accordance with § 319.56-2d of this subpart.

(g) *Plant pests; authorized treatments.*

(1) Apples from Belgium, Denmark, France, Great Britain, Italy, the Netherlands, Northern Ireland, Norway, Portugal, the Republic of Ireland, Sweden, Switzerland, and West Germany; and pears from Belgium, France, Great Britain, Italy, the Netherlands, Portugal, and Spain may be imported into the United States only if they are found free of the following pests or, if an authorized treatment is available, they are treated for the pest under the supervision of a PPQ inspector: and the pear leaf blister moth (*Leucoptera malifoliella* (O.G. Costa)(Lyonetiidae)), the plum fruit moth (*Cydia funebrana* (Treitschke)(Tortricidae)), the summer fruit tortrix moth (*Adoxophyes orana* (Fischer von Rosslerstamm)(Tortricidae)), a leaf roller (*Argyrotaenia pulchellana* (Haworth) (Tortricidae)), and other insect pests that do not exist in the United States or that are not widespread in the United States.

(2) Authorized treatments are listed in the Plant Protection and Quarantine Treatment Manual. The Plant Protection and Quarantine Treatment Manual is incorporated by reference. For the full identification of this standard, see § 300.1 of this chapter, "Materials incorporated by reference."

(h) *Inspection in the United States.* Notwithstanding provisions to the contrary in paragraphs (c) and (d) of this section, the Administrator may allow apples or pears imported under this section to be inspected at a port of arrival in the United States, in lieu of a preclearance inspection, under the following conditions:

(1) The Administrator has determined that inspection can be accomplished at the port of arrival without increasing the risk of introducing insect pests into the United States;

(2) Each pallet of apples or pears must be completely enclosed in plastic, to prevent the escape of insects, before it is offloaded at the port of arrival;

(3) The entire shipment of apples or pears must be offloaded and moved to an enclosed warehouse, where adequate inspection facilities are available, under the supervision of PPQ inspectors.

(4) The Administrator must determine that a sufficient number of inspectors

are available at the port of arrival to perform the services required.

(5) The method of inspection will be the same as prescribed in paragraph (d) of this section for preclearance inspections.

Done in Washington, DC, this 2nd day of December 1987.

James W. Glosser,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 87-27969 Filed 12-2-87; 12:31 pm]

BILLING CODE 3410-34-M

Agricultural Marketing Service

7 CFR Part 907

[Navel Orange Reg. 662]

Navel Oranges Grown in Arizona and Designated Part of California; Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: Regulation 662 establishes the quantity of California-Arizona navel oranges that may be shipped to market during the period December 4 through December 10, 1987. Such action is needed to balance the supply of fresh navel oranges with the demand for such oranges during the period specified due to the marketing situation confronting the orange industry.

EFFECTIVE DATE: Regulation 662 (§ 907.962) is effective for the period December 4 through December 10, 1987.

FOR FURTHER INFORMATION CONTACT: Raymond C. Martin, Section Head, Volume Control Programs, Marketing Order Administration Branch, F&V, AMS, USDA, Room 2528-S, P.O. Box 96456, Washington, DC 20090-6456; telephone: (202) 447-5120.

SUPPLEMENTARY INFORMATION: This final rule is issued under Marketing Order 907 (7 CFR Part 907), as amended, regulating the handling of navel oranges grown in Arizona and designated part of California. This order is effective under the Agricultural Marketing Agreement Act of 1937, as amended, hereinafter referred to as the Act.

This final rule has been reviewed under Executive Order 12291 and Departmental Regulation 1512-1 and has been determined to be a "non-major" rule under criteria contained therein.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of the

use of volume regulations on small entities as well as larger ones.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 123 handlers of California-Arizona navel oranges subject to regulation under the navel orange marketing order, and approximately 4,065 producers in California and Arizona. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.2) as those having annual gross revenues for the last three years of less than \$100,000, and small agricultural service firms are defined as those whose gross annual receipts are less than \$3,500,000. The great majority of handlers and producers of California-Arizona navel oranges may be classified as small entities.

This action is consistent with the marketing policy for 1987-88 adopted by the Navel Orange Administrative Committee (Committee). The Committee met publicly on December 1, 1987, in Los Angeles, California, to consider the current and prospective conditions of supply and demand and recommended, by an 8 to 3 vote, a quantity of navel oranges deemed advisable to be handled during the specified week. The Committee reports that the market for navel oranges is stabilizing.

Based on consideration of supply and market conditions, and the evaluation of alternatives to the implementation of prorate regulations, the Administrator of the AMS has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

Pursuant to 5 U.S.C. 553, it is further found that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice and engage in further public procedure with respect to this action and that good cause exists for not postponing the effective date of this action until 30 days after publication in the *Federal Register* because of insufficient time between the date when information became available upon which this regulation is based and the effective date necessary to effectuate the declared purposes of the Act. Interested persons were given

an opportunity to submit information and views on the regulation at an open meeting. To effectuate the declared purposes of the Act, it is necessary to make this regulatory provision effective as specified, and handlers have been apprised of such provision and the effective time.

List of Subjects in 7 CFR Part 907

Marketing agreements and orders, California, Arizona, Oranges (navel).

For the reasons set forth in the preamble, 7 CFR part 907 is amended as follows:

PART 907—[AMENDED]

1. The authority citation for 7 CFR Part 907 continues to read as follows:

Authority: Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.

2. Section 907.962 is added to read as follows:

§ 907.962 Navel Orange Regulation 662.

The quantity of navel oranges grown in California and Arizona which may be handled during the period December 4, 1987, through December 10, 1987, is established as follows:

- (a) District 1: 1,840,000 cartons;
- (b) District 2: Unlimited cartons;
- (c) District 3: 120,000 cartons;
- (d) District 4: 40,000 cartons.

Dated: December 2, 1987.

Robert C. Keeney,
Deputy Director, Fruit and Vegetable
Division, Agricultural Marketing Service.
[FR Doc. 87-28023 Filed 12-3-87; 8:45 am]
BILLING CODE 3410-02-M

7 CFR Part 910

(Lemon Reg. 590)

Lemons Grown in California and Arizona; Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: Regulation 590 establishes the quantity of fresh California-Arizona lemons that may be shipped to market at 325,000 cartons during the period December 6 through December 12, 1987. Such action is needed to balance the supply of fresh lemons with market demand for the period specified, due to the marketing situation confronting the lemon industry.

EFFECTIVE DATE: Regulation 590 (§ 910.890) is effective for the period December 6 through December 12, 1987.

FOR FURTHER INFORMATION CONTACT: Raymond C. Martin, Section Head,

Volume Control Programs, Marketing Order Administration Branch, F&V, AMS, USDA, Room 2523, South Building, P.O. Box 96456, Washington, DC 20090-6456; telephone: (202) 447-5697.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed under Executive Order 12291 and Departmental Regulation 1512-1 and has been determined to be a "non-major" rule under criteria contained therein.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

The purpose of the RFA is to fit regulatory action to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Agricultural Marketing Agreement Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

This regulation is issued under Marketing Order No. 910, as amended (7 CFR Part 910) regulating the handling of lemons grown in California and Arizona. The order is effective under the Agricultural Marketing Agreement Act (the "Act", 7 U.S.C. 601-674), as amended. This action is based upon the recommendation and information submitted by the Lemon Administrative Committee and upon other available information. It is found that this action will tend to effectuate the declared policy of the Act.

This regulation is consistent with the marketing policy for 1987-88. The committee met publicly on December 1, 1987, in Los Angeles, California, to consider the current and prospective conditions of supply and demand and recommended, by an 11 to 1 vote, a quantity of lemons deemed advisable to be handled during the specified week. The committee reports that the demand for lemons is good.

Pursuant to 5 U.S.C. 553, it is further found that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice, and engage in further public procedure with respect to this action and that good cause exists for not postponing the effective date of this action until 30 days after publication in the *Federal Register* because of insufficient time between the date when information became available upon which this regulation is

based and the effective date necessary to effectuate the declared purposes of the Act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting. It is necessary, in order to effectuate the declared purposes of the Act, to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

List of Subjects in 7 CFR Part 910

Marketing agreements and orders, California, Arizona, Lemons.

For the reasons set forth in the preamble, 7 CFR Part 910 is amended as follows:

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

1. The authority citation for 7 CFR Part 910 continues to read as follows:

Authority: Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.

2. Section 910.890 is added to read as follows:

§ 910.890 Lemon Regulation 590.

The quantity of lemons grown in California and Arizona which may be handled during the period December 6 through December 12, 1987, is established at 325,000 cartons.

Dated: December 2, 1987.

Robert C. Keeney,
Deputy Director, Fruit and Vegetable
Division, Agricultural Marketing Service.
[FR Doc. 87-28022 Filed 12-3-87; 8:45 am]
BILLING CODE 3410-02-M

DEPARTMENT OF THE TREASURY

Comptroller of the Currency

12 CFR Part 4

[Docket 87-13]

Description of Office, Procedures, Public Information

AGENCY: Comptroller of the Currency, Treasury.

ACTION: Final rule.

SUMMARY: The Office of the Comptroller of the Currency (Office) has completed the realignment of the major functions of the Washington Office. Also, Office address changes have been made in several of the districts. The final rule defines the current Washington supervisory and management positions, and lists the current addresses of the district offices.

EFFECTIVE DATE: December 4, 1987.

FOR FURTHER INFORMATION CONTACT:

Ferne Fishman Rubin, Attorney, Legal Advisory Services Division, (202) 447-1880, Office of the Comptroller of the Currency, 490 L'Enfant Plaza East, SW., Washington, DC, 20219.

SUPPLEMENTARY INFORMATION:

A reorganization of the Washington Office staff has been implemented. The major changes instituted by the reorganization include the creation of a Senior Deputy Comptroller for Bank Supervision Policy and a Senior Deputy Comptroller for Bank Supervision Operations; the incorporation of all functions involving industry, financial and economic research and planning into one department under the new Deputy Comptroller of Economic Analysis and Strategic Planning; and the consolidation of all administrative functions under the Senior Deputy Comptroller for Administration. In addition, the addresses of most district offices have been changed.

Notice and Comment

The Office has determined that notice and comment are unnecessary under 5 U.S.C. 553(b)(3)(A) since this final rule pertains to rules of agency organization and procedure.

Reason for Immediate Effective Date

This final rule informs the public about a change in office organization that has already occurred. Confusion could result if the proper titles and addresses are not employed immediately.

Regulatory Flexibility Act

A Regulatory Flexibility Analysis is required only for rules issued for notice and comment. Because this final rule pertains to office organization and is therefore exempt from notice and comment procedures, no Regulatory Flexibility Analysis will be prepared.

Executive Order 12291

Section 1(a)(3) of Executive Order 12291 exempts from coverage regulations related to agency organization, management, or personnel. Since this final rule is so classified, no Regulatory Impact Analysis is required.

List of Subjects in 12 CFR Part 4

National Banks, Organization and Functions (government agencies), Public information, Official forms, District offices, Field offices, Procedures, Delegation.

For the reasons given in the preamble, Part 4 of Chapter I, Title 12 of the Code of Federal Regulations is amended as follows:

PART 4—DESCRIPTION OF OFFICE, PROCEDURES, PUBLIC INFORMATION

1. The authority citation for Part 4 continues to read as follows:

Authority: 12 U.S.C. 1 *et seq.*, 5 U.S.C. 552, unless otherwise noted.

2. In Part 4, § 4.1a is amended by revising paragraphs (a), (b)(1), (2), (3) introductory text and (3)(vii) to read as follows:

§ 4.1a Central and field organization; delegations.

(a) *Central Office*—(1) *Comptroller of the Currency.* The Comptroller of the Currency, as head of the Office of the Comptroller of the Currency, is the chief regulatory officer for national banks and federally licensed branches and agencies of foreign banks. The Comptroller is responsible for directing the development, execution, and review of all Office programs and functions. The Comptroller is appointed by the President, by and with the advice and consent of the Senate, for a term of 5 years. The Comptroller's office is located at 490 L'Enfant Plaza East, SW., Washington, DC 20219. The Comptroller is assisted by the following officials who perform such duties as the Comptroller may prescribe in addition to the responsibilities set forth below.

(2) *Senior Deputy Comptroller for Legislative and Public Affairs.* The Senior Deputy Comptroller for Legislative and Public Affairs directs and coordinates external communications with banks and banking organizations, Congress, the public, news media, bank customers and nonbank financial industry groups. In addition, the Senior Deputy Comptroller oversees the internal communications program and the Community Development Corporation program. The Director of Banking Relations, the Director of Communications, the Director of Customer and Industry Affairs and the Director of Congressional Liaison are supervised by the Senior Deputy Comptroller for Legislative and Public Affairs.

(3) *Senior Deputy Comptroller for Bank Supervision Policy.* The Senior Deputy Comptroller for Bank Supervision Policy formulates, implements and monitors supervisory and compliance policies and procedures; conducts analyses of international banking issues; formulates rehabilitative solutions for troubled and failing banks; and coordinates the Office's supervisory systems and information activities. The Senior Deputy Comptroller for Bank Supervision Policy also coordinates the Comptroller's responsibilities as a member of the Board of Directors of the

Federal Deposit Insurance Corporation. The Deputy Comptroller for Special Supervision, the Deputy Comptroller for Supervisory Systems, the Chief National Bank Examiner, the Deputy Comptroller for Compliance and the Deputy Comptroller for International Relations and Financial Evaluation are supervised by the Senior Deputy Comptroller for Bank Supervision Policy.

(4) *Senior Deputy Comptroller for Bank Supervision Operations.* The Senior Deputy Comptroller for Bank Supervision Operations formulates, implements and monitors a broad range of policies and procedures relevant to the effectiveness and efficiency of the Office's six district offices and the Multinational Banking Department. The District Deputy Comptrollers and the Deputy Comptroller for Multinational Banking are supervised by the Senior Deputy Comptroller for Bank Supervision Operations.

(5) *Senior Deputy Comptroller for Corporate and Economic Programs.* The Senior Deputy Comptroller for Corporate and Economic Programs advises the Comptroller on policy matters, develops and implements programs relevant to the corporate activities and strategic planning components of the Office, conducts economic research and financial analyses, and is the primary decisionmaker responsible for national bank charter and merger applications and other national bank applications relating to corporate activities. The Deputy Comptroller for Bank Organization and Structure and the Deputy Comptroller for Economic Analysis and Strategic Planning are supervised by the Senior Deputy Comptroller for Corporate and Economic Programs.

(6) *Senior Deputy Comptroller for Administration.* The Senior Deputy Comptroller for Administration is responsible for the efficient administrative functioning of the district and Washington offices, which includes coordinating resource management, and directing all activities relating to information systems and technology, all external audit liaison activities, and the equal opportunity program. The Deputy Comptroller for Resource Management and the Deputy Comptroller for Systems and Financial Management are supervised by the Senior Deputy Comptroller for Administration.

(7) *Chief Counsel.* The Chief Counsel serves as the chief legal officer for the Office and is responsible for advising the Comptroller on all legal matters concerning the functions, activities, and operations of the Office and of all

national banks. The Chief Counsel is head of the Washington Law Department and supervises the District Counsel in each of the six district offices. The Deputy Chief Counsel (Operations) and Deputy Chief Counsel (Policy) are supervised by the Chief Counsel.

(8) *Special Adviser to the Comptroller.* The Special Adviser provides the Comptroller with advice and assistance on banking matters and policy issues, including the long-range implications of new developments and trends in the banking and financial industries. The Special Adviser also represents the Comptroller at key business and industry leader meetings.

(9) *Special Assistance.* The Special Assistants report directly to the Comptroller and provide administrative, liaison, and technical support for the Comptroller and the executive management of the Office.

(10) *Deputy Comptroller for Special Supervision.* The Deputy Comptroller for Special Supervision has managerial responsibility for programs dealing with banks which require special supervisory attention. The Deputy Comptroller for Special Supervision also formulates alternative solutions for the rehabilitation of troubled and failing banks, and works with Congress and other federal regulators to implement these solutions.

(11) *Deputy Comptroller for Supervisory Systems.* The Deputy Comptroller for Supervisory Systems oversees the design, development, enhancement, and maintenance of supervisory information systems and information activities; coordinates and promotes the development of analytical techniques using advanced technology; and fosters confidence in supervisory processes and information through a quality improvement process.

(12) *Chief National Bank Examiner.* The Chief National Bank Examiner formulates, implements and monitors supervisory policies, programs and projects; keeps Washington and district office staffs advised of current bank supervisory policy and issues; oversees the banking industry's use of computer technology; and coordinates activities relating to the establishment of accounting principles and reporting practices for national banks.

(13) *Deputy Comptroller for Compliance.* The Deputy Comptroller for Compliance manages the formulation, implementation and monitoring of the Office's compliance program, and oversees all compliance-related activities including trust, consumer and investment securities activities.

(14) *Deputy Comptroller for International Relations and Financial Evaluation.* The Deputy Comptroller for International Relations and Financial Evaluation oversees the development of the Office's international relationships and communication networks, and research on policies, regulation and legislation pertaining to international activities of national banks. The Deputy Comptroller for International Relations and Financial Evaluation also provides advice and recommendations in the international area to the Office's senior management, Treasury and other government agencies.

(15) *Deputy Comptroller for Multinational Banking.* The Deputy Comptroller for Multinational Banking has managerial responsibility for programs dealing with multinational bank activities, including responsibility for international and multinational bank examinations. The Deputy Comptroller for Multinational Banking also directs all supervisory activities in the nation's largest national banks and foreign banks with Federal licenses, and coordinates the analysis of a wide variety of corporate proposals.

(16) *Deputy Comptroller for Bank Organization and Structure.* The Deputy Comptroller for Bank Organization and Structure establishes and implements policies affecting corporate activities of national banks, and reviews requests from individuals and banks to engage in banking activities.

(17) *Deputy Comptroller for Economic Analysis and Strategic Planning.* The Deputy Comptroller for Economic Analysis and Strategic Planning analyzes and monitors the national banking system, coordinates the strategic and operations planning activities of the Office, and analyzes major policy issues and presents recommendations via studies, briefings and congressional testimony.

(18) *Deputy Comptroller for Resource Management.* The Deputy Comptroller for Resource Management directs the implementation of policies and procedures for the functions of human resources, training and development, operations analysis, equal-employment programs, and administrative services.

(19) *Deputy Comptroller for Systems and Financial Management.* The Deputy Comptroller for Systems and Financial Management coordinates the Office's information systems program, the development and administration of data, and all financial management activities.

(20) *Deputy Chief Counsel (Operations).* The Deputy Chief Counsel (Operations) is responsible for the Litigation, the Enforcement and Compliance, and the Securities and

Corporate Practices Divisions of the Office's Law Department.

(21) *Deputy Chief Counsel (Policy).* The Deputy Chief Counsel (Policy) is responsible for the Legal Advisory Services, and the Legislative and Regulatory Analysis Divisions of the Office's Law Department, as well as the District Counsels.

(b) *Field organization.* (1) Six district offices cover the United States, Puerto Rico, the Virgin Islands, Guam and the Northern Mariana Islands. The office address and the geographical composition of each district follows:

District and area within district	Office address
Northeastern: Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Puerto Rico, Rhode Island, Vermont, Virgin Islands.	Comptroller of the Currency, 1211 Avenue of the Americas, Suite 4250, New York, NY 10036.
Western: Alaska, Arizona, California, Colorado, Guam, Hawaii, Idaho, Montana, Nevada, Northern Mariana Islands, Oregon, Washington, Wyoming, Utah.	Comptroller of the Currency, 50 Fremont Street, Suite 3900, San Francisco, CA 94105.
Central: Illinois, Indiana, Kentucky, Michigan, Ohio, Wisconsin.	Comptroller of the Currency, One Financial Place, Suite 2700, 440 South LaSalle Street, Chicago, IL 60605.
Southwestern: Arkansas, Louisiana, New Mexico, Oklahoma, Texas.	Comptroller of the Currency, 1600 Lincoln Plaza, 500 N. Akard Street, Dallas, TX 75201.
Southeastern: Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, West Virginia.	Comptroller of the Currency, Marquis One Tower, Suite 600, 245 Peachtree Center Avenue, NE, Atlanta, GA 30303.
Midwestern: Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota.	Comptroller of the Currency, 12345 Grand Avenue, Suite 700, Kansas City, MO 64108.

(2) Twenty-three field offices located in financial centers throughout the country support bank supervisory responsibilities of the districts.

(3) Each district office is headed by two senior executives, a Deputy Comptroller and a District Administrator.

In addition, the office structure includes a District Counsel and Directors for Administration, Bank Supervision, and Analysis.

(vii) The Field Office Director, although not in the district office, works closely with district directors, supervises field examiners assigned to the relevant geographical area, coordinates other supervisory functions, and serves as liaison between bankers,

examiners, and the District Administrator.

Dated: November 24, 1987.

Robert L. Clarke,

Comptroller of the Currency.

[FR Doc. 87-27888 Filed 12-3-87; 8:45 am]

BILLING CODE 4810-33-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 76-CE-32-AD; Amdt. 39-5794]

Airworthiness Directives; Beech 99 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment revises Airworthiness Directive (AD) 77-05-01R2, Amendment 39-4237, applicable to certain serial numbers of the Beech 99 Series airplanes, by adding a reference to the Aerocon California Service Letter dated May 25, 1976, which is essential to the spar strap inspections required by paragraph (V)(A)(1) of the AD. In addition, this revision corrects a previous error of including the phrase "or later approved revisions" in reference to the Service Instructions listed in the AD.

DATES: *Effective Date:* December 8, 1987.

Compliance: As prescribed in the body of the AD.

ADDRESSES: Beechcraft Service Instructions 0388-018, Rev. VI or Rev. VII, may be obtained from Beech Aircraft Corporation, Commercial Service, Department 52, P.O. Box 85, Wichita, Kansas 67201; Telephone (316) 681-9111. Aerocon California, Inc. Engineering Order No. E.O. B-9975-2, dated November 14, 1975, and Service Letter dated May 25, 1976, may be obtained from Western Aircraft Maintenance, 4444 Aeronca Street, Boise, Idaho 83705. This information may be examined at the Rules Docket, Office of the Regional Counsel, FAA,

Room 1558, 601 East 12th Street, Kansas City, Missouri 64106.

FOR FURTHER INFORMATION CONTACT:

Don Campbell, Aerospace Engineer, Airframe Branch, ACE-120W, Wichita Aircraft Certification Office (ACO), 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; Telephone (316) 946-4409.

SUPPLEMENTARY INFORMATION:

Airworthiness Directive (AD) 77-05-01R2, Amendment 39-4237 (46 FR 52090; October 26, 1981) applicable to certain serial numbers of Beech 99 Series airplanes, requires inspection of wing main spar lower cap and associated structure for fatigue cracking, and limits the safe life of this structure. Revision 1 to the AD removed the safe life limit if a spar strap is installed per Supplemental Type Certificate (STC) SA1178CE, provided the strap be removed periodically and the structure and strap be inspected per the AD. Revision 2 exempted airplanes which have Beech Kit 99-4023-1S (Superspar) installed. Proper inspection of the strap must include a check for strap tensile preload as described in Aerocon California Service Letter dated May 25, 1976. Subsequent to the issuance of this AD, and Revisions 1 and 2, it was discovered that no reference to strap tensioning was included in the AD.

Therefore, the FAA is revising AD 77-05-01R2 by specifying spar strap tension checks per the applicable STC maintenance information. In addition, the phrase "or later approved revisions" is being deleted from the AD. The latest service information is correctly referenced in the AD.

This amendment clarifies a rule that, if misunderstood or incorrectly applied, could result in loss of the aircraft. Therefore, notice and public procedure hereon are unnecessary, contrary to the public interest, and good cause exists for making this amendment effective in less than 30 days.

The FAA has determined that this regulation is an emergency regulation that is not major under Section 8 of Executive Order 12291. It is impracticable for the agency to follow the procedure of Order 12291 with respect to this rule since the rule must

be issued immediately to correct an unsafe condition in aircraft.

It has been further determined that this document involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required). A copy of it, when filed, may be obtained by contacting the Rules Docket under the caption "ADDRESSES" at the location identified.

List of Subjects in 14 CFR Part 39

Air transportation, Aviation safety, Aircraft, Safety

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the FAR as follows:

PART 39—[AMENDED]

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By revising and reissuing AD 77-05-01R2, Amendment 39-4237 (46 FR 52090; October 26, 1981), as follows:

Beech: Applies to Model 99 (Serial Numbers U-1 through U-49 and U-51 through U-164) series airplanes with 3,000 or more hours' time in service except those airplanes which have Beech Wing Modification Kit No. 99-4023-1S installed:

Compliance: Required as indicated in accordance with the compliance tables set forth in this AD or as otherwise specified herein, unless already accomplished. To detect any cracking of the wing front spar lower cap, other wing panel front spar carry-through structural components, wing remaining structure or STC SA1178CE wing straps, accomplish the following:

1. Front spar lower cap inspection requirements:

TABLE 1.—COMPLIANCE TIMES

Lower spar cap, total time in service	Inspection times	
	Initial inspection in accordance with this AD	Interval for repetitive inspections
0-2,999	None	None
3,000-7,500	Within 100 hours' time in service after accumulation of 3,000 hours' time in service or within 600 hours' time in service after last comparable inspection in accordance with AD 75-27-10.	Each 500 hours (X-ray included).
7,500-Up to 10,000 hours or to spar cap life limit time extension.	Within 600 hours' time in service after last comparable inspection in accordance with AD 75-27-10.	Each 300 hours except X-ray at 600 hour intervals.

A. Inspect, at time intervals noted in Table 1 above, the structural components set forth in Part I of Beechcraft Service Instructions 0388-018, Rev. VI or Rev. VII, and summarized below, using those visual, dye penetrant, eddy current and x-ray methods of inspection set forth in Part I of said service instructions:

1. The right and left lower forward inboard and outboard wing attachment fittings;
2. The lower forward wing fitting-to-spar attachment area and the edges of the forward

and aft flanges on the lower forward spar cap in the center section, outboard of each main gear wheel well;

3. The lower forward spar cap in each main gear wheel well;

4. The lower surface of the lower forward spar cap in the nacelle inboard of each main gear wheel well;

5. The four 3/16-inch brazier head rivets on the lower side of the spar cap in the nacelle inboard of each main gear wheel well;

6. The lower surface of the lower forward spar cap between each nacelle and the fuselage; and

7. The four Jo-bolt holes in the forward flange of the lower forward spar cap inboard of each nacelle in the area of the wing root rib.

II. Wing carry-through components inspection requirements:

TABLE 2.—COMPLIANCE TIME

Aircraft total time in service	Inspection times	
	Initial inspection in accordance with this AD	Interval for repetitive inspections
0-2,999	None	None.
3,000-7,500	Within 100 hours' time in service after the accumulation of 3,000 hours' time in service or within 600 hours' time in service after the last comparable inspection in accordance with AD 75-27-10.	Each 500 hours.
7,501-and on	Within 600 hours' time in service after the last comparable inspection in accordance with AD 75-27-10.	Each 300 hours thereafter.

A. Inspect, at time intervals noted in Table 2 above, using visual methods, the structural components set forth in Paragraph o. of Part I of Beechcraft Service Instructions 0388-018,

Rev. VI or Rev. VII, and summarized below:

1. The fuselage center line skin in the area between the forward and aft center section spars, and

2. The two fuselage formers aft of the forward center section spar.

III. Wing remaining structure inspection requirements:

TABLE 3.—COMPLIANCE TIMES

Aircraft total time in service	Inspection times	
	Initial inspection in accordance with this AD	Interval for repetitive inspections
0-9,999	None	None.
10,000-17,500	Within 600 hours' time in service after the effective date of this AD or at attainment of life limit of original spar cap. These times apply regardless of whether STC SA1178CE is or is not installed.	Each 500 hours.
17,501 and on	Within 400 hours' time in service after the effective date of this AD, or at attainment of life limit of original spar cap. These times apply regardless of whether STC SA1178CE is or is not installed.	Each 300 hours thereafter for aircraft that did not have life limit extensions granted. Each 500 hours beyond the extended life of the spar and then at 300 hour intervals thereafter for aircraft that had life limit extensions granted.

A. Inspect, at time intervals noted in Table 3 above, using visual and dye penetrant methods of inspection, the structural components set forth in Part III of Beechcraft Service Instructions 0388-018, Rev. VI or Rev. VII, and summarized below:

1. Lower fuselage skin at attachment to the forward spar;
 2. Lower skin of each nacelle;
 3. Center section skin under the top fairing and around the upper attach flange in each nacelle;
 4. Upper flange of keel assembly doubler at the outboard side of each wheel well where the keel attaches to the main spar;
 5. Dimpled skin attach holes on the forward side of the main spar at four Jo-bolts, left and right, and at all rivets between the fuselage and each nacelle;
 6. Top skin attachment to the aft spar;
 7. Lower aft spar cap and skin;
 8. Lower strap on front spar at left and right wing stations 68.5;
 9. Three stringers nearest the fuselage centerline between spars;
 10. Frames and angle clips of the center wing/fuselage at fuselage stations 188, 197, and 207;
 11. Four upper forward and eight aft wing-to-center section fittings;
 12. Outer wing upper and lower forward spar cap and hinge; and
 13. Aft spar and ribs near inboard flaps.
- IV. Wing front spar lower cap replacement requirements:

A. On all airplanes, except those having front spar lower cap straps installed in accordance with STC SA1178CE, (1) upon accumulation of 10,000 hours' front spar lower cap time in service or (2) 10,000 hours' time in service after replacing the front spar lower cap and associated components in accordance with Paragraph VI and (3) at 10,000 hours' time in service intervals thereafter, or at the attainment of service life extensions granted prior to January 7, 1976, replace the structural components set forth in Part II of Beechcraft Service Instructions 0388-018, Rev. VI or Rev. VII, and summarized below:

1. Lower cap of the front spar, with attachment fitting, in each outer wing panel, and
2. Lower cap of the front spar, with left and right attachment fittings, in the center section.

V. Wing inspection requirements for airplanes having front spar lower cap straps installed per STC SA1178CE:

A. (Front spar lower cap and STC straps):
Within 1,000 hours' time in service after installation of above noted STC straps (if front spar lower cap had 1,000 or more hours' time in service at time of strap installation) and thereafter at intervals not to exceed 1,000 hours' time in service or within 2,000 hours' time in service after installation of above noted STC straps (if front spar lower caps had 999 or less hours' time in service at time of strap installation) and thereafter at intervals not to exceed 2,000 hours' time in service:

1. Remove and inspect STC SA1178CE straps in accordance with Aerocon California, Inc. Engineering Order No. E.O. B-9975-2, dated November 14, 1975, and adjust the strap tension (preload) per Aerocon

California Service Letter dated May 25, 1976, and

2. Inspect wing front spar lower cap and associated components in accordance with Paragraph I and Items 5 and 8 of Paragraph III of this AD.

B. (Wing carry-through components):

Inspect wing carry-through components at the time intervals specified in and per the requirements of Paragraph II of this AD.

C. (Wing remaining structure):

Inspect wing remaining structure at the time interval specified and per the requirements of Paragraph III of this AD except that compliance is not required with respect to Items 5, 8 and that portion of Item 12 which refers to the lower spar cap and hinge as specified in said Paragraph III.

VI. If a crack or loose fastener is found during any inspection required by this AD, prior to further flight, accomplish the repair or replacement specified by the applicable portion of Beechcraft Service Instruction 0388-018, Rev. VI or Rev. VII, or in accordance with Aerocon California, Inc. Engineering Order No. E.O. B-9975-2 dated November 14, 1975.

VII. Aircraft maintenance record entries must be made and notification in writing sent to the Manager, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Room 100, Wichita, Kansas 67209, stating the location and length of any cracks found during inspections required by this AD and also the total time in service of the component at the time the crack was discovered. Reports may be submitted by letter or through M or D or MRR procedures. (Reporting approved by the Office of Management and Budget under OMB No. 2120-0056.)

VIII. Within two (2) days after each x-ray inspection, send the radiographs by most rapid means for review and comment to Beech Aircraft Corporation, Wichita, Kansas 67201.

IX. The eddy current inspections required by this AD must be performed by personnel who have received training and are qualified in the operation of eddy current equipment and this equipment must be calibrated using a specimen obtained from the manufacturer which simulates cracking of the spar cap. The replacement of critical parts such as the spar caps and wing attach fittings required by this AD must be performed by personnel or facilities properly equipped and certificated to perform such repairs.

X. Aircraft may be flown in accordance with FAR 21.197 to a base where this AD can be accomplished.

XI. The inspection intervals set forth in Tables 1, 2 and 3 and elsewhere in this AD may be adjusted up as much as 25 hours where required to fit users maintenance cycles if authorized by local FAA Flight Standards Inspectors.

XII. Life limit time extensions, for wing front spar lower cap and associated fittings, (also called components) granted in writing prior to January 7, 1976, apply only to those components that were in the aircraft when the time extension was granted and do not apply to new components installed after the extended life limits are attained.

XIII. Equivalent methods of compliance with this AD, if used, must be approved by

the Manager, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Room 100, Wichita, Kansas 67209; Telephone (316) 946-4400.

All persons affected by this directive may obtain copies of the documents referred to herein upon request to Beech Aircraft Corporation, Commercial Service, Department 52, Wichita, Kansas 67201-0085, or Western Aircraft Maintenance, 4444 Aeronca Street, Boise, Idaho 83705, or examined at FAA, Office of the Regional Counsel, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106.

This AD supersedes AD 75-27-10 (Amendment 39-2484).

Amendment 39-2843 became effective April 7, 1977.

Amendment 39-3357 became effective November 17, 1978.

Amendment 39-4237 became effective October 13, 1981.

This amendment revises AD 77-05-01R2, Amendment 39-4237.

This amendment becomes effective December 8, 1987.

Issued in Kansas City, Missouri, on November 23, 1987.

Paul K. Bohr,

Director, Central Region.

[FR Doc. 87-27838 Filed 12-3-87; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 87-NM-95-AD; Amdt. 39-5798]

Airworthiness Directives; British Aerospace Model H.S. 748 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to all Model H.S. 748 series airplanes, which requires a visual inspection of certain bearings in the rudder spring tab, flap torque shaft assemblies, and flap interference roller, and repair, if necessary. This amendment is prompted by a report that bearings in these installations may be improperly retained. This condition, if not corrected, could lead to excessive wear and/or loss of function of the affected systems.

EFFECTIVE DATE: January 25, 1988.

ADDRESSES: The applicable service information may be obtained from British Aerospace, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041. This information may be

examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT:

Ms. Judy Golder, Standardization Branch, Seattle Aircraft Certification Office, ANM-113; telephone (206) 431-1967. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION:

A proposal to amend Part 39 of the Federal Aviation Regulations to include an airworthiness directive, applicable to British Aerospace Model H.S. 748 series airplanes, which requires visual inspection for looseness of certain bearings (held in place by bearing retention rings) installed in the rudder spring tab, flap torque shaft assemblies, and flap interference roller, and repair, if necessary, was published in the *Federal Register* on August 20, 1987 (52 FR 31410).

Interested parties have been afforded an opportunity to participate in the making of this amendment. No comments were received in response to the proposal.

After careful review of the available data, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

It is estimated that 2 airplanes of U.S. registry will be affected by this AD, that it will take approximately 2 manhours per airplane to accomplish the required actions, and that the average labor cost will be \$40 per manhour. Based on these figures, the total cost impact of this AD to U.S. operators is estimated to be \$160.

For the reasons discussed above, the FAA has determined that this regulation is not considered to be major under Executive Order 12291 or significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and it is further certified under the criteria of the Regulatory Flexibility Act that this rule will not have a significant economic effect on a substantial number of small entities, because of the minimal cost of compliance per airplane (\$80). A final evaluation has been prepared for this regulation and has been placed in the docket.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator,

the Federal Aviation Administration amends § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By adding the following new airworthiness directive:

British Aerospace: Applies to all Model H.S. 748 series airplanes, as listed in the BAe Service Bulletin 27/110, dated November 1986, certificated in any category. Compliance is required within 60 days after the effective date of this AD unless previously accomplished.

To prevent interference caused by loose bearings, accomplish the following:

A. Inspect the bearing installations of the rudder spring tab, flap torque shaft assemblies, and flap interference roller in accordance with BAe Service Bulletin 27/110, dated November 1986. Any bearing installation found to be loose must be repaired prior to further flight, in accordance with the BAe service bulletin.

B. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of inspections and/or modifications required by this AD.

All persons affected by this proposal who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to British Aerospace, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041. These documents may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or at the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

The amendment becomes effective January 25, 1988.

Issued in Seattle, Washington, on November 27, 1987.

Wayne J. Barlow,

Director, Northwest Mountain Region.

[FR Doc. 87-27840 Filed 12-3-87; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 87-NM-103-AD; Amdt. 39-5799]

Airworthiness Directives; British Aerospace Model H.S. 748 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to all British Aerospace Model H.S. 748 series airplanes with Modification 1472 incorporated, but without Modification 7513 incorporated, which requires replacement of certain nose landing gear jack support bracket bearing cap attachment studs. This amendment is prompted by reports of incidents where the nose landing gear has malfunctioned due to the failure of the nose landing gear jack support bracket bearing cap attachment studs. This condition, if not corrected, could result in the inability to lower or lock down the nose gear for landing.

EFFECTIVE DATE: January 25, 1988.

ADDRESSES: The applicable service information may be obtained from British Aerospace, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041. This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT:

Mr. Henry A. Jenkins, Systems and Equipment Branch, ANM-130S; telephone (206) 431-1946. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation Regulations to include an airworthiness directive which requires inspection and replacement of nose landing gear jack support bracket bearing cap attachment studs on certain British Aerospace Model H.S. 748 airplanes, was published in the *Federal Register* on September 10, 1987 (52 FR 34227).

Interested parties have been afforded an opportunity to participate in the making of this amendment. No comments were received in response to the NPRM.

Paragraph F. of the final rule has been revised to require the concurrence of the

FAA Principal Maintenance Inspector in requests by operators for use of alternate means of compliance. The FAA has determined that this change will not increase the economic burden on any operator, nor will it increase the scope of the AD.

After careful review of the available data, the FAA has determined that air safety and public interest require the adoption of the rule with the change discussed above.

It is estimated that 3 airplanes of U.S. registry will be affected by this AD, that it will take approximately 0.2 manhours per airplane to accomplish the required actions, and that the average labor cost will be \$40 per manhour. Based on these figures, the total cost impact of this AD on U.S. operators is estimated to be \$24.

For the reasons discussed above, the FAA has determined that this regulation is not considered to be major under Executive Order 12291 or significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and it is further certified under the criteria of the Regulatory Flexibility Act that this rule will not have a significant economic effect on a substantial number of small entities, because of the minimal cost per airplane (\$8). A final evaluation has been prepared for this regulation and has been placed in the docket.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

1. The authority citation 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By adding the following new airworthiness directive:

British Aerospace: Applies to all Model H.S. 748 series airplanes with Modification 1472 incorporated, but without Modification 7513 incorporated, certificated in any category. Compliance required as indicated, unless previously accomplished.

To prevent inability to lower or lock down the nose gear for landing, accomplish the following:

A. Prior to the accumulation of 7,000 landings or within the next 90 days after the effective date of this AD, whichever occurs later, replace nose landing gear jack support

bracket bearing cap attachment studs, Part Number 2cD13248, in accordance with British Aerospace Alert Service Bulletin A53/53 Revision 1, dated May 1987.

B. Replacement studs must, in turn, be replaced prior to accumulation of 7,000 landings.

C. Until studs exceeding a life of 7,000 landings have been replaced, nose landing gear jack support structure must be inspected prior to each day's first flight to ensure each stud and bearing cap are secure and correctly fitted in accordance with British Aerospace Alert Service Bulletin A53/53, Revision 1, dated May 1987.

D. On assemblies where the bearing caps or studs are found loose, all four bearing cap attachment studs must be replaced before the next flight, in accordance with British Aerospace Alert Service Bulletin A53/53, Revision 1, dated May 1987.

E. Incorporation of Modification 7513, as described in British Aerospace Alert Service Bulletin A53/53, Revision 1, dated May 1987, constitutes terminating action for requirements of paragraphs A., B., C., and D., above.

F. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety and which has the concurrence of an FAA Principal Maintenance Inspector, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

G. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of inspections and/or modifications required by this AD.

All persons affected by this directive who have not already received the appropriate service information from the manufacturer may obtain copies upon request to British Aerospace, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041. This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or at the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective January 25, 1988.

Issued in Seattle, Washington on November 27, 1987.

Wayne J. Barlow,

Director, Northwest Mountain Region.

[FR Doc. 87-27841 Filed 12-3-87; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 87-NM-75-AD; Amdt. 39-5797]

Airworthiness Directives; Fokker Model F27 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Fokker Model F27 series airplanes, which requires modification of the rudder trim tab. This amendment is prompted by reports of rudder trim tab flutter. This condition, if not corrected, could result in loss of the trim tab and damage to the rudder.

EFFECTIVE DATE: January 25, 1988.

ADDRESSES: The applicable service information may be obtained from Fokker Aircraft USA, Inc., 1199 N. Fairfax Street, Alexandria, Virginia 22314. This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Ms. Judy Golder, Standardization Branch, ANM-113; telephone (206) 431-1967. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation Regulations to include an airworthiness directive, which requires modification of the rudder trim tab to prevent flutter on certain Fokker Model F27 series airplanes, was published in the Federal Register on July 10, 1987 (52 FR 26022). That action was prompted by several reports of rudder trim tab flutter, which could result in the loss of the trim tab and damage to the rudder.

Interested parties have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the single comment received.

The commenter stated that he had not experienced any flutter problems, and questioned the need for an AD. The commenter also pointed out that the service difficulty program has cited no reports of flutter from January 1, 1987, through August 1, 1987. No U.S. operator, to the commenter's knowledge, has experienced rudder flutter, and the manufacturer has stated the existing rudder tab is flutter free if its integrity is maintained in accordance with present maintenance recommendations. The commenter proposed a mandatory repetitive inspection, in lieu of the modification, to assure tab integrity. The FAA does not concur with the comment that an AD is not necessary. The FAA has determined that the AD is justified because non-U.S. operators have

experienced seven instances of flutter; while U.S. operators have not experienced a flutter problem, the potential for such a problem still exists. The repetitive inspection program recommended by the commenter may be submitted for consideration as an alternate means of compliance as stated in Paragraph B. of this AD.

After careful review of the available data, including the comments discussed above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

It is estimated that 38 airplanes of U.S. registry will be affected by this AD, that it will take approximately 80 manhours per airplane to accomplish the required actions, and that the average labor cost will be \$40 per manhour. The cost of parts is estimated at \$1600 per airplane. Based on these figures, the total cost impact of this AD on U.S. operators is estimated to be \$182,400.

For the reasons discussed above, the FAA has determined that this regulation is not considered to be major under Executive Order 12291 or significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979) and it is further certified under the criteria of the Regulatory Flexibility Act that this rule will not have a significant economic effect on a substantial number of small entities because of the minimal cost of compliance per airplane (\$4800). A final evaluation has been prepared for this regulation and has been placed in the docket.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

1. The authority citation for Part 39 to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By adding the following new airworthiness directive:

Fokker B.V.: Applies to Fokker Model F27 series airplanes, serial numbers 10102 through 10684, 10686, 10687, 10689 through 10692, certificated in any category. Compliance required within one year after the effective date of this AD, unless previously accomplished.

To prevent flutter of rudder trim tab, accomplish the following:

A. Modify the rudder trim tab in accordance with Part 2, Accomplishment Instructions, of Fokker Service Bulletin No. F27/55-62, dated August 18, 1986, or Revision 1, dated April 15, 1987.

B. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of the modifications required by this AD.

All persons affected by this directive who have not already received the appropriate service document from the manufacturer may obtain copies upon request to Fokker Aircraft USA, Inc., 1199 N. Fairfax Street, Alexandria, Virginia 22314. This document may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective January 25, 1988.

Issued in Seattle, Washington, on November 27, 1987.

Wayne J. Barlow,
Director, Northwest Mountain Region.
[FR Doc. 87-27843 Filed 12-3-87; 8:45 am]
BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 87-ASW-50; Amdt. 39-5786]

Airworthiness Directives;
Messerschmitt-Bolkow-Blohm Models
BO-105 and BK-117, All Series; Bell
Helicopter Textron, Inc., Model 222, All
Series; and Aerospatiale Model AS-
355, All Series; Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action publishes in the Federal Register and makes effective as to all persons an amendment adopting a new airworthiness directive (AD) which was previously made effective as to all known U.S. owners and operators of certain Messerschmitt-Bolkow-Blohm (MBB) Model BO-105, all series, with STC No. SH479GL installed; MBB Model BK-117, all series, with STC No. SH1853SO installed; Bell Helicopter Textron Inc., Model 222, all series, with STC No. 1879SO installed; and Aerospatiale Model AS-355, all series, with STC No. SH673GL installed, by individual priority letter AD. This AD requires the removal of engine

compartment labels. This AD is needed to prevent ingestion of the labels by the engine which could result in complete loss of engine power.

DATES: *Effective Date:* December 18, 1987, as to all persons except those persons to whom it was made immediately effective by priority letter AD 87-19-01, issued September 8, 1987, which contained this amendment.

Compliance: Required before further flight after the effective date of this AD, unless already accomplished.

ADDRESSES: Service Bulletin No. 081987, dated August 19, 1987, may be obtained from Facet Enterprises, Inc., 8439 Triad Drive, Greensboro, NC 27409.

A copy of the Service Bulletin is contained in the Rules Docket, Federal Aviation Administration, Southwest Region, Office of the Regional Counsel, 4400 Blue Mound Road, Fort Worth, Texas.

FOR FURTHER INFORMATION CONTACT: Jerry C. Robinette, Aerospace Engineer, Propulsion Branch, ACE-140A, Atlanta Aircraft Certification Office, Federal Aviation Administration, Central Region, 1669 Phoenix Parkway, Suite 210C, Atlanta, Georgia 30349; telephone (404) 991-3810.

SUPPLEMENTARY INFORMATION: On September 8, 1987, priority letter AD 87-19-01 was issued and made effective immediately to all known U.S. owners and operators of certain MBB Model BO-105 and BK-117, all series; Bell Helicopter Textron, Inc., Model 222, all series; and Aerospatiale Model AS-355, all series; helicopters. The AD requires the removal of an advisory label which can become debonded from the airframe. AD action was necessary to prevent ingestion of the label by an engine.

Since it was found that immediate corrective action was required, notice and public procedure thereon were impracticable and contrary to public interest, and good cause existed to make this AD effective immediately by individual priority letter AD, issued September 8, 1987, to all known U.S. owners and operators of certain MBB Model BO-105 and BK-117, all series; Bell Helicopter Textron, Inc., Model 222, all series; and Aerospatiale Model AS-355, all series; helicopters. These conditions still exist, and the AD is hereby published in the Federal Register as an amendment to § 39.13 of Part 39 of the Federal Aviation Regulations (FAR) to make it effective as to all persons.

The FAA has determined that this regulation is an emergency regulation that is not considered to be major under Executive Order 12291. It is

impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation or analysis is not required). A copy of it, when filed, may be obtained by contacting the person identified under the caption "**FOR FURTHER INFORMATION CONTACT.**"

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration (FAA) amends § 39.13 of Part 39 of the Federal Aviation Regulations (FAR) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); 14 CFR 11.89.

§ 39.13 [Amended]

2. By adding the following new airworthiness directive (AD):

Messerschmitt-Bolkow-Blohm (MBB), Bell Helicopter Textron, Inc., and Aerospatiale: Applies to all MBB BO-105, all series, with STC No. SH479GL installed; MBB Model BK-117, all series, with STC No. SH1853SO installed; Bell Model 222, all series, with STC No. SH1879SO installed; Aerospatiale Model AS-355, all series, with STC No. SH673GL installed.

Compliance is required before further flight, unless already accomplished.

To prevent the ingestion of the labels (Facet P/N's 1741120 and 1741120-01) by the engines, accomplish the following:

(a) Gain access to the engine compartment where the labels are located.

(b) Remove the labels (Facet P/N's 1741120 and 1741120-01) from the airframe using methyl ethyl ketone (MEK) and a single-edge razor.

(c) Clean area where label was installed.

(d) Make appropriate logbook entry showing compliance with this AD.

(e) An alternative method of compliance which provides an equivalent level of safety may be used when approved by the Manager, FAA Atlanta Aircraft Certification Office,

1669 Phoenix Parkway, Suite 210C, Atlanta, Georgia 30349.

(f) Aircraft may be ferried in accordance with the provisions of FAR 21.197 and FAR 21.199 to a base where the AD can be accomplished.

Note.—1. The information on the labels repeats information which is provided in the Rotorcraft Flight Manual Supplement.

2. Facet Service Bulletin No. 081987, dated August 19, 1987, refers to this subject.

This amendment becomes effective December 18, 1987, as to all persons except those persons to whom it was made immediately effective by priority letter AD 87-19-01, issued September 8, 1987, which contained this amendment.

Issued in Fort Worth, Texas, on November 19, 1987.

Don P. Watson,

Acting Director, Southwest Region.

[FR Doc. 87-27839 Filed 12-3-87; 8:45 am]

BILLING CODE 4910-13-M

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 1

Fees for Rule Enforcement and Financial Reviews

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule and final schedule of fees.

SUMMARY: The Commission recently proposed a revision to its method of calculating annual fees for rule enforcement, sales practice and financial reviews of exchanges. 52 FR 28284 (July 29, 1987). The fees would be set at 65% of the actual average cost of reviewing each exchange over a three-year period. The Commission is now adopting the proposed formula and 1987 fee schedule in final form as proposed.

EFFECTIVE DATE: February 2, 1988.

FOR FURTHER INFORMATION CONTACT:

Gerry Smith, Office of the Executive Director, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581. Telephone: (202) 254-6090.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Futures Trading Act of 1982 (Pub. L. 97-444, 96 Stat. 2294, 2326, January 11, 1983) amended section 26 of the Futures Trading Act of the 1978 (7 U.S.C. 16a) to add specific authority for the Commission—

to promulgate, after notice and opportunity for hearing, a schedule of appropriate fees to

be charged for services rendered and activities and functions performed by the Commission in conjunction with its administration and enforcement of the Commodity Exchange Act; *Provided*, That the fees for any specified service or activity or function shall not exceed the actual cost thereof to the Commission

The Conference Report accompanying the legislation (H.R. Rep. No. 964, 97th Cong. 2d Sess. 57 (1982)) states that "the conferees intend that the fee schedule addressed by the Congress be strictly limited to Commission activities directly related to" eight enumerated Commission functions including "contract market and registered futures association rule enforcement reviews and financial reviews."

On January 8, 1985, the Commission promulgated a final schedule of fees for contract market and rule enforcement reviews. 50 FR 928. Under this schedule, the fee for each exchange was based on both the trading volume of the exchange and the number of contracts traded on the exchange during the preceding three fiscal years. The Commission prospectively estimated that both of these factors had a direct effect on the amount of time Commission staff spent conducting reviews of each exchange. 49 FR 22827, 22828 (June 1, 1984).

On July 29, 1987, the Commission published a proposed revision to the formula and a proposed schedule of fees for FY 1987 based on this new formula. 51 FR 28284. Under the proposed formula and exchange's annual fee will be 65% of the actual average cost of reviewing that exchange over a three-year period, rounded to the nearest multiple of \$100.

The Commission proposed this revision in order to insure that it will consistently recover 65% of its actual cost of reviewing each exchange. Under the existing fee schedule, the Commission's total recovery of its actual review costs through fees paid by the exchanges was falling significantly each year. In FY 1985, the Commission recovered 69% of its actual review costs. In FY 1986 the Commission received 64% of its costs, and in FY 1987, under the previous fee schedule, the Commission would have received only 53% of its costs.

The previous fee schedule also resulted in the exchanges paying different percentages of the actual cost of Commission review. The revised fee schedule will guarantee that each exchange's fee represents the same percentage of the actual cost to the Commission of reviewing that exchange. As a result, the review fees will operate like the Commission's other service fees, which are also based on actual costs.

The new method of calculating fees will produce a narrower range of fee changes. The Commission incurs certain costs in reviewing any exchange, regardless of its size. Although these costs increase as the size of the exchange increases, they do not do so in a linear manner. The new method of calculating fees reflects this "base level" by tying fees to actual costs and, as a result, the fees charged different sized exchanges under the new method of calculating fees will vary from one exchange to another to a lesser extent than under the current system.

One commenter supported the proposal, but recommended that the Commission consider a four-year rather than a three-year average in order to minimize year-to-year fluctuations in the fee. The Commission has decided to retain the three-year average at this time. However, it is not necessarily opposed to considering a four-year average in the future.

Another commenter supported the Commission's proposed use of actual costs, but expressed concern about the possibility of unchecked future escalation of fees and suggested that a cap on fees be established. The Commission believes that by limiting fees to 65% of actual costs, it has established a reasonable limitation on fees. The 65% level was intended to maintain a level of collection closer to what was originally achieved under the old formula (69%) while at the same time distributing fees more equitably based on the actual cost of reviewing each exchange. It is likely that the actual costs of review will rise as the Commission's personnel and overhead costs increase. Therefore, it can be expected that the fee for rule enforcement, sales practice and financial review will rise in subsequent years.

A third commenter opposed the Commission's proposal. This commenter and the second commenter both expressed concern about the effect of these fees on the ability of domestic markets to compete with foreign exchanges, partly because the exchange will pass any increase in fees on to market users. The Commission does not believe that the change in the method of calculating rule enforcement review fees will have an impact on international competition. There is little evidence that fees have an effect on the volume of trading. Since NFA fees and CFTC service fees were imposed in 1983, the volume of trading has increased by over 85%.

The third commenter also asserted that the proposed fee schedule would motivate exchanges to merge in order to

avoid the cost of review. The Commission has not seen any evidence that existing NFA or CFTC fees have been the cause of mergers, nor does it believe that the fees proposed are large enough to create an incentive for merger.

The same commenter also contends that the new formula will have a "chilling effect" on the review process because the new formula does not use the "neutral" factor of volume as the basis for the calculation. The commenter suggests that by using actual costs as a basis for the fee, the CFTC will discourage the exchange from conducting complex investigations of possible violations of exchange rules, from engaging in dialogue with CFTC staff during a review and from challenging CFTC's conclusions in the final stages of a review because of the time consumed by each of those activities. The Commission disagrees with this assessment. In general, the Commission does not believe that the level of fees that would be imposed on exchanges reasonably could be expected to be a determinant of exchange self-regulatory activities as contended by the commenter. Moreover, an exchange's failure to conduct complex investigations can result in more rather than less Commission resources being devoted to review of an exchange's affirmative compliance program than if an exchange does conduct such investigations. For example, it may be necessary for the Commission to conduct more frequent reviews supplemented by increased informal oversight to assure that an exchange fulfills its self-regulatory responsibilities.

The third commenter further questions whether the new formula would be based on readily available, verifiable information. In response, the Commission will obtain actual costs, which are the basis of the revised formula, from the Budget Account Code (BAC) system print-outs of the hours logged by CFTC staff on review of each exchange, along with a calculation of associated costs based on the actual salaries of those employees. These figures are verifiable as are the figures used in the calculation of overhead costs derived from the Commission's accounting system.

The same commenter also makes reference to the variability in the number of hours expended on reviews. While in the past the staff audited some exchanges less frequently than others, as a matter of practice, a report usually is issued on each exchange every two years. In order to operate on this schedule, the rule enforcement review

and sales practice audit staff undertake an audit every two years, while the financial audit staff visit an exchange more frequently to conduct different segments of a review.

This commenter also pointed out that, in two instances, actual costs were divided evenly between three New York exchanges. In FY 1984 an equal cost of \$3,088 was charged to Comex, the Coffee, Sugar and Cocoa Exchange and the New York Cotton Exchange. In FY 1985 an equal cost of \$15,532 was charged to the Coffee, Sugar and Cocoa Exchange, the New York Mercantile Exchange and the New York Cotton Exchange. The total costs were divided evenly between the exchanges because actual costs of auditing the exchanges were erroneously recorded under a single budget code (22400) rather than under separate codes for each exchange. The Commission has decided to remove these costs from its calculations, as the commenter suggests. Therefore, the fees for Comex, the Coffee, Sugar and Cocoa Exchange, the New York Cotton Exchange, and the New York Mercantile Exchange have been reduced in the final schedule of fees.

The Commission has concluded that it is appropriate to include the charge the commenter refers to as a "market surveillance" fee. In conjunction with rule enforcement reviews conducted by the staff of the Division of Trading and Markets, the staff of the Division of Economic Analysis periodically assists in the review of exchange market surveillance programs. Generally, in these instances, the Division of Economic Analysis staff uses the Division of Trading and Markets' BAC codes, but in the course of a review of one exchange, spanning FY 1985 and FY 1986, the New York Division of Economic Analysis staff used their own code. Because the time recorded by the Economic Analysis staff under the code was a legitimate part of a rule enforcement review, the Commission has included these costs in the total cost of the rule enforcement review of the exchange involved.

The commenter suggests alternative fee calculations based on varying ratios between volume and actual cost. Volume has not proven to be an accurate measure of the costs to the government of conducting rule enforcement and financial reviews. Each of the alternatives offered by the commenter would result in several exchanges paying more than actual costs, a result which the Commission has concluded would be inappropriate.

Finally, this commenter requested that the Commission hold a hearing on the

proposed service fees. The commenter cited section 26(c) of the Futures Trading Act of 1978 as authority for this request. In pertinent part section 26(c) provides that:

Nothing in this section shall limit the authority of the Commission to promulgate, after notice and opportunity for hearing, a schedule of appropriate fees to be charged for services rendered and activities and functions performed by the Commission in conjunction with its administration and enforcement of the Commodity Exchange Act

Where, as here, a statute provides that an agency may promulgate regulations after "notice and opportunity for a hearing," the hearing may consist of a notice and comment procedure, and need not be an oral or "trial-type" hearing. See *United States v. Florida East Coast Railway Co.*, 410 U.S. 224, 235-38 (1973). Under the Administrative Procedure Act, trial-type hearings are required only if the relevant statute directs that the agency make its decision after a hearing "on the record." See *id.*; see also *Farmer's Union Central Exchange, Inc. v. Federal Energy Regulatory Commission*, 734 F.2d 1486, 1499 n.39 (D.C. Cir. 1984); *Pacific Coast European Conference v. United States*, 350 F.2d 197, 205 (9th Cir. 1965). Section 26(c) does not require that the Commission hold a hearing "on the record" when it promulgates fee schedules. Consequently, the notice and comment procedure provided by the Commission constitutes a legally sufficient hearing under the statute. Therefore, the Commission is denying the commenter's request for an oral hearing.

The Commission has therefore determined to adopt the rule amendment as proposed. The computation of the FY 1987 fee under the revised rule follows.

II. Computation of Fees for FY 1987

Under the final rule, fees are calculated by first extracting personnel costs recorded by staff for rule enforcement and financial reviews from the Budget Account Code (BAC) system for a three-year period, in this case FY 1984, FY 1985 and FY 1986. The Commission then adds an overhead factor for benefits, including retirement, insurance and leave, based on a government-wide standard, and an overhead factor for general and administrative costs, such as space, equipment and utilities. The overhead figure is derived by computing the percentage of Commission appropriations spent on these non-personnel items.

As noted in the *Federal Register* release on the proposed rule, the Commission applied a total overhead factor of 45% to costs incurred through

FY 1984. Subsequently, the overhead factor was changed in accordance with OMB Circular A-76. This change in the overhead factor resulted in calculations of 98% overhead for FY 1985 and 104% overhead for FY 1986. Minor fluctuations in overhead are expected from year to year as there are changes in government-wide benefits and in the percentage of Commission appropriations applied to non-personnel costs.

Once the total personnel costs for reviewing each exchange and overhead costs were determined, the costs for FY 1984, FY 1985 and FY 1986 were averaged to calculate the average annual cost of reviewing each exchange over the three-year period. That figure was then multiplied by 65% and rounded to the nearest multiple of \$100 to arrive at the FY 1987 fee for that exchange.

The FY 1987 fee for each exchange follows. The fee is due 60 days after publication of this notice.

	Actual avg. costs— FY 1984— FY 1986	FY 1987 fee under proposed rule
Chicago Board of Trade ¹	\$166,592	\$108,300
Chicago Mercantile Exchange	153,828	100,000
Commodity Exchange, Inc.	75,440	49,000
Coffee, Sugar & Cocoa Exchange	47,016	30,600
New York Mercantile Exchange	74,318	48,300
New York Cotton Exchange	68,703	44,700
Kansas City Board of Trade	43,017	28,000
New York Futures Exchange	55,243	35,900
Minneapolis Grain Exchange	30,820	20,000
Philadelphia Board of Trade	2,034	1,300
Amex Commodities Corp.	4,399	2,900
Total	721,410	469,000 (65%)

¹ The Chicago Board of Trade, the Mid-America Exchange and the Chicago Rice and Cotton Exchange are combined solely for the purpose of determining the rule enforcement review fee.

III. Regulatory Flexibility Act

The changes proposed in this release affect contract markets (also referred to as "exchanges"). The Commission has previously determined that contract markets are not "small entities" for purposes of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, 47 FR 18618 (April 30, 1982). Therefore, the requirements of the Regulatory

Flexibility Act do not apply to contract markets. Accordingly, the Chairman, on behalf of the Commission, certifies that the fees proposed herein do not have a significant economic impact on a substantial number of small entities.

List of Subjects in 17 CFR Part 1

Contract market rule reviews,
Contract market financial reviews, Fees.

For the reasons set out in the preamble, Title 17, Part 1, Appendix B, is amended as set forth below.

PART 1—GENERAL REGULATIONS UNDER THE COMMODITY EXCHANGE ACT

1. The authority citation for Part 1 is revised to read as follows:

Authority: 7 U.S.C. 2, 2a, 4, 4a, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6j, 6k, 6l, 6m, 6n, 6o, 7, 7a, 7b, 8, 9, 12, 12a, 12c, 13a, 13a-1, 16, 16a, 19, 21 and 24 unless otherwise noted.

2. Paragraph (b) of Appendix B is revised to read as follows:

Appendix B—Fees for Contract Market Rule Enforcement Reviews and Financial Reviews

(b) The Commission shall compute the annual fee for each board of trade by computing the actual average annual cost to the Commission of conducting rule enforcement and financial reviews of that board of trade over the preceding three fiscal years, then multiplying that amount by 65% and rounding to the nearest multiple of \$100.

Issued in Washington, DC, on December 1, 1987, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 87-27878 Filed 12-3-87; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 271

[Docket Nos. GP87-69-000, GP87-66-000, GP87-68-000]

Final Order Approving Jurisdictional Agency Determinations

Issued November 25, 1987.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final order approving jurisdictional agency determinations.

SUMMARY: On November 25, 1987, the Commission issued a final order in the captioned dockets affirming the recommendations of the Colorado Oil and Gas Conservation Commission and the Virginia Department of Mines, Minerals and Energy that certain areas be designated as tight formations pursuant to § 271.703(c)(2)(i) of the Commission's regulations and the provisions of the Natural Gas Policy Act of 1978. In the order, the Commission directs that § 271.703(d) of the Commission's regulations be amended by adding paragraphs (201), (202) and (203), describing the areas designated as tight formations. The jurisdictional agencies of Colorado and Virginia have submitted for Commission review recommendations of areas to be designated as tight formations.

EFFECTIVE DATE: November 25, 1987.

FOR FURTHER INFORMATION CONTACT:

Ray J. Alvarez, Federal Energy Regulatory Commission, Office of the General Counsel, 825 North Capitol Street NE., Washington, DC 20426, (202) 357-8316.

SUPPLEMENTARY INFORMATION:

Order No. 485

Before Commissioners: Martha O. Hesse, Chairman; Anthony G. Sousa, Charles G. Stalon, Charles A. Traband and C.M. Naeve. High-Cost Gas Produced From Tight Formations; Colorado Oil & Gas Conservation Commission (Colorado-38 Addition), Docket Nos. GP87-69-000 (formerly RM79-76-255); Colorado Oil & Gas Conservation Commission (Colorado-39 Addition), Docket Nos. GP87-68-000 (formerly RM79-76-239); Virginia Department of Mines, Minerals and Energy, (Virginia-4), Docket Nos. GP87-68-000 (formerly RM79-76-249).

The Colorado Oil and Gas Conservation Commission (Colorado and the Virginia Department of Mines, Minerals and Energy (Virginia) have submitted to the Commission in the captioned dockets recommendations that certain areas be designated as tight formations pursuant to § 271.703(c)(2)(i) of the Commission's regulations and the provisions of the Natural Gas Policy Act of 1978 (NGPA). Under section 107(c)(5) of the NGPA the Commission is authorized to prescribe incentive prices for high-cost natural gas. High-cost gas is produced under conditions which present extraordinary risks or costs and once designated may receive an incentive price. The Commission

determined that natural gas produced from tight formations is high-cost natural gas under section 107(c)(5).¹ Under the Commission's regulations (18 CFR 271.703) jurisdictional agencies may submit for Commission review recommendations of areas to be designated as tight formations.

The Commission in the past has reviewed tight formation recommendations under its general rulemaking authority as provided for by NGPA section 501. However, the United States Court of Appeals for the District of Columbia Circuit recently held in *Williston Basin Interstate Pipeline Co. v. FERC*, 816 F.2d 777 (D.C. Cir. 1987) that the Commission must review jurisdictional agency tight formation recommendations as determinations under NGPA section 503. On July 29, 1987, the Commission revised its regulations pertaining to tight formation gas in Order No. 479, 40 FERC ¶ 61,103 (1987), so that pending tight formation recommendations (such as these) would be considered as jurisdictional agency determinations under section 503 of the NGPA. Section 503 of the NGPA prescribes that if substantial evidence is lacking to support a jurisdictional agency's determination, the Commission may issue a preliminary finding reversing such determination. A final order must be issued within 120 days thereafter.

After reviewing the data originally submitted to Colorado and Virginia, the Commission staff submitted deficiency letters to both agencies requesting more detailed information. No responses were received. On July 29, 1987 the Commission issued a notice of preliminary finding under section 503(b) of the NGPA, 40 FERC ¶ 61,102 (1987), that the determinations by Colorado and Virginia were not supported by substantial evidence in the record on which the determinations were made. The notice of preliminary finding provided that jurisdictional agencies, interested parties, or any person could, within 30 days after issuance of the preliminary finding, submit written comments and request an informal conference with the Commission staff.

In response to the preliminary finding, Colorado has submitted additional evidence in support of its recommendations and Virginia has

amended its tight formation recommendation, all as reported below. Based on the additional information and amendment, the Commission will approve the jurisdictional agency determinations.

Colorado-38 Addition (GP87-69-000, formerly RM79-76-255)

On February 9, 1987, Colorado submitted a recommendation that the Niobrara tight formation designation be extended to include additional lands in Larimer, Boulder and Weld Counties, Colorado. Other portions of the Niobrara formation had previously been recommended as a tight formation by Colorado and approved by the Commission in Order No. 386, 27 FERC ¶ 61,471 (1984). On June 4, 1987, the Commission staff advised Colorado that more information was needed to support the recommendation. Since a majority of the wells in the recommended area appear to be oil wells, Colorado was requested to clarify whether the recommended area contains designated oil fields and, if so, why Colorado believes the oil areas should be designated as a natural gas tight formation. Staff also requested additional information such as well completion reports and pre and post-stimulation production data to substantiate Colorado's finding that the flow rates of oil and gas were not expected to exceed the levels specified in the Commission's regulations. No reply was forthcoming, and the Commission issued its preliminary finding on July 29, 1987, that the recommendation was not supported by substantial evidence in the record.

Two comments were received during the 30 day comment period. On August 25, 1987, Mian Petroleum Services, Inc. submitted additional data and a letter of concurrence from Colorado that the data supports its conclusion that the recommended area be designated a tight formation. On the basis of this additional information the Commission concurs with Colorado's finding.

Colorado's recommendation is based on geological and engineering data from eight wells located in the proposed area. Permeability values were estimated using horizontal flow equations from four wells. The following are arithmetic averages derived from data submitted in support of the tight formation designation:

(1) Based on data from four wells, the average core permeability throughout

¹ Order No. 99, Regulations Covering High-Cost Natural Gas Produced from Tight Formations, 45 FR 56,034 (Aug. 22, 1980), FERC Stats. and Regs. [Regulations Preambles 1977-1987] ¶ 30,183 (1980).

the pay section is expected to be 0.0203 millidarcy, which is less than the maximum allowable *in situ* permeability of 0.1 millidarcy;

(2) Based on testimony before Colorado, the pre-stimulation flow rate is expected to be between zero and 15 Mcf per day, which is less than the maximum allowable of 163 Mcf per day;

(3) No well drilled in the Niobrara formation is expected to produce, without stimulation, more than five barrels of crude oil per day.

These conclusions support Colorado's finding that the recommended formation satisfies the guidelines for tight formations set forth in § 271.703(c)(2)(i) of the regulations.

Colorado-39 Addition (GP87-66-000, formerly RM79-76-239)

On November 15, 1984, Colorado submitted a recommendation that the Niobrara formation located in Weld County, Colorado, be designated as a tight formation. The recommended acreage is an extension of an area in which the Niobrara formation had been previously approved as a tight formation by the Commission in Docket No. RM79-76-235 (Colorado-39). On April 18, 1985, the Commission staff advised Colorado that additional information was required in order to review Colorado's recommendation. The staff noted that the record contained no permeability data for wells in the recommended area and requested Colorado to furnish such permeability data. If no data were available, staff requested that Colorado explain why data derived from five wells outside the recommended area was adequate to support the recommendation. Colorado was also requested to provide additional information such as well completion reports and production data to substantiate Colorado's recommendation that the flow rates are not expected to exceed those specified in the regulations. No reply was forthcoming, and the Commission issued its preliminary finding on July 29, 1987, that the recommendation was not supported by substantial evidence in the record.

In response to the preliminary finding, Colorado provided additional information on August 19, 1987 pertaining to Niobrara permeability and production rates in the proposed area. As explained in this supplemental report, there is still no Niobrara permeability data currently obtainable within the recommended area. However, Niobrara core data from wells located just outside the area reveal an average permeability of 0.086 millidarcy. In this area, as well as in the recommended

area, geological and engineering data was provided to show that the depth of burial for the Niobrara is approximately 6,000 to 7,000 feet. At such depth, chalk matrix porosities are generally 10% and permeabilities are expected to be .01-.03 millidarcy. Therefore, by knowing both porosity and depth of burial for the Niobrara within the recommended area, the data clearly indicates that the *in situ* permeability is expected to be 0.1 millidarcy or less. Colorado also provided data to show that the pre-stimulation flow rate within the recommended area is zero. A well test conducted within the area showed that Niobrara flows only after stimulation with hydrochloric acid, sand and water. Based on the additional data submitted, the Commission is satisfied that there is now substantial evidence in the record to support Colorado's tight formation recommendation.

Virginia-4 (GP87-68-000, formerly RM79-76-249)

On May 12, 1986, Virginia recommended that the "Big Lime" formation in southwest Virginia in portions of Buchanan, Dickenson, Lee, Scott, Wise, Russell, and Tazewell Counties be designated as a tight formation. By letter dated September 29, 1986, Commission staff advised Virginia that its recommendation, as it pertains to the "Big Lime" formation in Buchanan County, was not supported by substantial evidence and that the Buchanan portion should be deleted from the recommendation. No response was forthcoming, and the Commission issued its preliminary finding on July 29, 1987, that the recommendation was not supported by substantial evidence in the record.

On October 29, 1987, in response to the Commission's preliminary finding, Virginia requested that Buchanan County be excluded from its "Big-Lime" recommendation. A review of the remaining areas of the "Big Lime" formation indicates that Virginia's recommendation, as amended, is supported by substantial evidence in the record and should therefore be approved.

The Commission Orders:

(A) Colorado's determinations that additional areas in the Niobrara formation qualify as tight formations under NGPA section 503 are affirmed.

(B) Virginia's determination that the "Big Lime" formation (as amended to exclude Buchanan County) qualifies as a tight formation under NGPA section 503 is affirmed.

(C) The Commission directs that § 271.703, paragraph (d) of the Commission's regulations be amended

by adding paragraphs (201), (202) and (203) to read as set forth below.

List of Subjects in 18 CFR Part 271

Natural gas, Incentive price, Tight formations.

In consideration of the foregoing, Part 271 of Subchapter H, Chapter I, Title 18, Code of Federal Regulations, is amended as set forth below.

By the Commission.

Lois D. Cashell,
Acting Secretary.

PART 271—CEILING PRICES

1. The authority citation for Part 271 continues to read as follows:

Authority: Natural Gas Act, 15 U.S.C. Secs. 717-717W (1982); Department of Energy Organization Act, 42 U.S.C. Secs. 7101-7352 (1982); E.O. 12009, 3 CFR 1978 Comp., p. 142; Natural Gas Policy Act of 1978; 15 U.S.C. Secs. 3301-3432 (1982).

2. In § 271.703, paragraph (d) is revised by adding paragraphs (201), (202) and (203) to read as follows:

§ 271.703 Tight formations.

* * * * *

(d) Designated tight formations * * *

(201) *Niobrara Formation in Colorado.* (Colorado-38 Addition).

(i) *Delineation of formation.* The Niobrara Formation is located in Weld County, Colorado, in Township 4 North, Range 68 West, Sections 7, 8, 17-20, 29-32, in Larimer County, Colorado, in Township 4 North, Range 69 West, Sections 11-14, 23-27, 34-36, and Township 3 North, Range 69 West, Sections 1-3, 6th P.M.

(ii) *Depth.* The Niobrara Formation underlies the Pierre Shale and overlies the Codell Formation. The top of the Niobrara Formation varies in depth from zero at 7,000 feet and averages 5,300 feet. The Niobrara Formation averages 225 feet in thickness.

(202) *Niobrara Formation in Colorado.* (Colorado-39 Addition).

(i) *Delineation of formation.* The Niobrara Formation is located in Weld County, Colorado, in Township 4 North, Range 64 West, 6th P.M., all Sections; Township 4 North, Range 65 West, 6th P.M., all Sections; Township 5 North, Range 64 West, 6th P.M., Sections 25 through 36; Townships 5 North, Range 65 West, 6th P.M., Sections 2 through 36; Township 5 North, Range 66 West, 6th P.M., Sections 1, 12, 13, and 36; and Township 6 North, Range 65 West, 6th P.M., Sections 31 and 32.

(ii) *Depth.* The Niobrara Formation is defined as that interval which begins at a depth of approximately 7,000 feet and varies in thickness from 250 feet to 350

feet. The Niobrara in this area is found between the bottom of the Sharon Springs Shale and the top of the Codell Sandstone.

(203) *The "Big Lime" Formation in Virginia.* (Virginia-4).

(i) *Delineation of formation.* The "Big Lime" Formation is located in the plateau region of southwestern Virginia and consists of most of Dickenson County and portions of Lee, Scott, Wise, Russell, and Tazewell Counties (maps showing the area are on file with the Commission).

(ii) *Depth.* The depth to the top of the formation ranges from above sea level along the Pine Mountain thrust exposure and on top of the Powell Mountain anticline near the northwest boundary to 1,950 feet below sea level to the south in Wise County. The formation ranges in thickness from 450 feet in the northwest to 950 feet toward the southeast.

[FR Doc. 87-27860 Filed 12-3-87; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 35a and 602

(T.D. 8163)

Imposition of Backup Withholding Due To Notification of an Incorrect Taxpayer Identification Number and the Due Diligence Exception to the Imposition of a Penalty for a Missing or an Incorrect Taxpayer Identification Number

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correction to temporary regulations.

SUMMARY: This document contains nonsubstantive corrections to Treasury Decision 8163, which was published in the *Federal Register* on Monday, November 23, 1987 (52 FR 44861). Treasury Decision 8163 issued temporary regulations on the requirement to backup withhold due to notification of an incorrect taxpayer identification number and on the due diligence exception to the penalty for a missing or an incorrect taxpayer identification number.

FOR FURTHER INFORMATION CONTACT: Renay France of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224, Attention: CC:LR:T (202-566-3829, not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On November 23, 1987, the *Federal Register* published a Treasury decision on the requirement to backup withhold due to notification of an incorrect taxpayer identification number and on the due diligence exception to the penalty for a missing or an incorrect taxpayer identification number.

Need for Correction

As published, Treasury Decision 8163 inadvertently fails to amend Part 602, OMB Control Numbers under the Paperwork Reduction Act, to insert the OMB reference number in the table under § 602.101(c).

Corrections of Publication

Accordingly, the publication of Treasury Decision 8163 is corrected as follows:

Paragraph 1. The list of subjects provision in the third column on page 44865 is amended to add the list of subjects under Part 602 immediately after the words "Dividend Tax Compliance Act of 1983." to read as follows:

List of Subjects in 26 CFR Part 602

Reporting and recordkeeping requirements.

Par. 2. In the third column on page 44865 the phrase "Accordingly 26 CFR Part 35a is amended as follows" is amended by adding an "s" to the word "Part", by inserting the words "and 602" immediately after "35a", and by striking the word "is" and inserting in its place the word "are".

Par. 3. Two new paragraphs 6 and 7 are added in the first column on page 44882 immediately after the last sentence in A-103 to read as follows:

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 6. The authority for Part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

§ 602.101 [Amended]

Par. 7. Section 602.101(c) is amended by inserting the following in the appropriate place in the table:

"§ 35a.3406-1 . . . 1545-0969".

Donald E. Osteen,

Director, Legislation and Regulations Division.

[FR Doc. 87-27804 Filed 12-3-87; 8:45 am]

BILLING CODE 4830-01-M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, 1926, and 1928

Hazard Communication; Display of Office of Management and Budget Control Numbers Assigned To Collection of Information

AGENCY: Occupational Safety and Health Administration (OSHA); Labor.

ACTION: Technical amendments.

SUMMARY: On August 24, 1987, OSHA published a final rule in the *Federal Register* entitled "Hazard Communication" (52 FR 31852). This document amends that rule by adding a control number assigned by the Director of the Office of Management and Budget (OMB) after each section of the Code of Federal Regulations in which the rule appears (29 CFR 1910.1200, 1915.99, 1917.28, 1918.90, and 1926.59). The Paperwork Reduction Act requires display of OMB control numbers with all information collection provisions.

In addition, this document reprints the text of a letter from OMB to the Department of Labor regarding OMB's review under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) of the information collection requirements of the Hazard Communication Standard. OSHA is reviewing the OMB letter, as well as the Agency's extensive rulemaking record on this subject, to determine the appropriate course of action.

DATES: These amendments are effective December 4, 1987. The OMB approval expires on May 23, 1988.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, 200 Constitution Avenue NW., Room N3637, Washington, DC 20210; telephone (202) 523-8151.

SUPPLEMENTARY INFORMATION: As described more fully in the text of the letter which follows, OMB has conditionally approved the information collection requirements of most of the provisions of the Hazard Communication Standard until May 23, 1988. OMB has disapproved, however, three requirements which were to take effect on that date. The assigned control numbers are indicated in the text of the amendments which follows the reprinted OMB letter. The Paperwork Reduction Act requires display of OMB

control numbers with all information collection provisions.

October 28, 1987

Honorable Thomas C. Komarek,
Assistant Secretary for Administration and
Management, Department of Labor,
Washington, DC 20210.

Dear Tom: Pursuant to the Paperwork Reduction Act (44 U.S.C. Chapter 35), we have completed our review of the collection of information requirements in the Occupational Safety and Health Administration's Hazard Communication Standard (HCS), which were submitted to us by your office on September 10, 1987. We notified the Department of our decision on October 23, 1987. This letter explains in greater detail our October 23rd decision and transmits the record of our October 16, 1987 public hearing on the HCS together with the written comments we have received.

As proposed by OSHA on March 19, 1982, and promulgated as a final rule on November 25, 1983, the HCS applied only to the manufacturing sector of the economy. Pursuant to a court order, OSHA promulgated on August 24, 1987 a new final HCS based on the record developed in response to the original proposal. This most recent final rule differs substantially from the original proposal because it applies to the non-manufacturing sector as well.

On September 10, 1987, you submitted for the first time the paperwork provisions in the revised final rule for OMB review. Thus, you asked us to reinstate previously approved paperwork covering the manufacturing sector, for which OMB approval expired on June 30, 1987, and to approve an additional 28.7 million hours of new paperwork covering the non-manufacturing sector. In addition, we are asked to approve new paperwork for the manufacturing sector that apparently went into effect 30 days after publication of the new final rule, without approval under the Paperwork Reduction Act.

Our review of the paperwork provisions in the expanded standard has confirmed our support and earlier approval of the original Hazard Communication Standard in 1983, and our belief in its importance in reducing occupational illnesses and injuries by ensuring that workers are informed about the hazards of substances to which they may be exposed on the job. As OSHA has long recognized, however, this deceptively simple goal becomes exceedingly complicated when applied to millions of different worksites, work conditions, and products across the country. I commend the Department for continuing to adopt a performance-oriented approach to hazard communication that allows employers flexibility in complying with the rule, and for tailoring the expanded rule to adapt the flow of information more appropriately to some of these worksites and products.

Decision

Your request for OMB review of the HCS paperwork provisions has raised difficult issues. The Department promulgated a final rule under an order from the U.S. Court of Appeals for the Third Circuit, but failed to follow the approval procedures required in Section 3504(h) of the Paperwork Reduction

Act. The explicit purpose of Section 3504(h) is to establish a mechanism to coordinate rulemakings and Paperwork Reduction Act reviews. Section 3504(h) allows OMB to disapprove any collection of information requirement where the agency has substantially modified in the final rule the collection of information requirement in the proposed rule if the agency has not submitted the modified requirement to OMB for review at least 60 days prior to issuance of the final rule. These procedures for prior review are intended to avoid the difficult situation in which, after rulemakings are completed, further rulemaking may be necessary if we cannot approve the paperwork components of the rule. The Department's failure to comply with these procedures prior to publication is particularly unfortunate given the Third Circuit's concern that the final rule not be further delayed. In the course of our review, we have carefully weighed our obligations under the Paperwork Reduction Act and the concern of the court that the final standard should take effect without unreasonable delay.

As you know, the Paperwork Reduction Act requires that agencies of the Federal government obtain OMB approval before conducting or sponsoring a collection of information. Under the Act and implementing regulations at 5 CFR 1320, we are required to determine that the paperwork requirements have practical utility, that they are the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives, and that they do not duplicate information otherwise available. Section 3512 of the Act protects the public from penalties resulting from failure to comply with collection of information requirements that are not approved under the Act.

During our review of the HCS, we conducted public meetings on the proposed paperwork provisions on April 2, 1987, and October 16, 1987, and reviewed numerous written comments. We have carefully analyzed this record, which provides additional information and new perspectives on the record upon which OSHA based the expanded rule, and, as required by the Act, have based our decision upon it. We have determined that the record does not support certain paperwork provisions and would not allow approval. Hence, pursuant to Section 3504(h)(5)(D) of the Paperwork Reduction Act and 5 CFR 1320.13(g) of the implementation regulations, we have disapproved, effective May 23, 1988, the following collection of information requirements:

- the requirement that material safety data sheets be provided on multi-employer worksites;
- coverage of any consumer product excluded from the definition of "hazardous chemical" under Section 311(e)(3) of the Superfund Amendments and Reauthorization Act of 1980;
- coverage of any drugs regulated by FDA in the non-manufacturing sector.

Our disapproval takes effect on May 23, 1988, the date on which the expanded standard takes effect for the non-manufacturing sector. In the rulemaking

required below, we believe the Department should take action under the Administrative Procedures Act to revise these requirements prior to the effective date (below, we suggest alternatives that may be consistent with the Paperwork Reduction Act) or collect new information that would warrant a reconsideration of our decision under the Paperwork Reduction Act.

We have approved all other paperwork requirements through May 23, 1988, but have determined that reconsideration of the definition of "article" is needed in order to achieve consistency with the Act. Therefore, pursuant to 1320.14 (f) and (g) of the implementing regulations, we are instructing the Department to complete a rulemaking on this and other issues, including issuance of a notice of proposed rulemaking and a final rule. The rulemaking shall examine, at least, alternatives to the definition of "article," including a *de minimis* exemption and clarification of the concept of "normal use," and should conform the provisions of the rule relating to the manufacturing sector to the requirements in the non-manufacturing sector in light of this decision. In the course of this rulemaking, the Department shall comply with Section 3504(h) procedures to accommodate the needs of both the Administrative Procedures Act and the Paperwork Reduction Act. Our approval is conditioned on adherence to the following schedule for consideration of these paperwork provisions:

December 1, 1987: Publication in the **Federal Register** of a notice of proposed rulemaking to reconsider certain paperwork provisions of the HCS and submission of paperwork to OMB for review

January 31, 1988: Public comment period on NPRM closes

March 1, 1988: Publication in the **Federal Register** of a final rule concerning the HCS; paperwork submitted to OMB for review

Although this schedule is tight, it is very important that OSHA conclude its rulemaking to revise the standard, giving OMB sufficient time to complete review of the final paperwork provisions and the public sufficient time to understand and implement the revisions prior to the effective date of the standard.

Generic Hazard Communication Programs

Many commenters spoke forcefully about widespread confusion in the regulated community, particularly among small businesses, regarding their responsibilities under the HCS. Some, for example, were unsure who would be responsible for the accuracy of the MSDS information—the generator or the downstream user (1-24). Others stated that a certification or technical assistance effort was needed to give employers confidence that their efforts were in compliance with the HCS. Still others mentioned that the Federal Government had developed a Federal Generic Hazard Communication program, which contains step-by-step instructions for implementing the HCS, a model written program, and an HCS training program, in order to reduce Federal agency costs in complying with the HCS, and that a similar approach may be

useful for the private sector. In fact, the single issue on which every commenter who addressed the issue agreed was the need for some sort of non-mandatory guidance from OSHA on the development of hazard communication programs (see e.g. comments by the Small Business Administration, the Organization of Resources Counselors, AFL-CIO, National Association of Home Builders, National LP-Gas Association, American Farm Bureau Federation, Associated General Contractors of America, Associated Builders and Contractors, National Association of Wholesaler-Distributors, Petroleum Marketers Association of America, National Automobile Dealers Association, National Paint and Coatings Association, and the American Subcontractors Association, Inc.).

These comments strongly suggest that administrative actions by OSHA could reduce the paperwork compliance burden associated with the information collection provisions. Although we do not have sufficient information to determine what administrative action would be most appropriate, we believe that OSHA should examine several options, while relying to the extent possible on the private sector. We believe OSHA should consider working with the appropriate public and private groups, as well as existing OSHA advisory groups, in developing a suitable approach. Options may include the development of a generic hazard communication program or guidelines suitable for the development of generic programs by the private sector and by States, which could perhaps be certified as meeting the requirements of the HCS. Certification of private sector generic programs would continue to encourage the private market to develop programs, while also offering the employer some guarantee that the program purchased meets OSHA's expectations for compliance. OSHA could also make available any generic guidelines that were developed to any employer wishing to design his or her own plan.

Such an administrative effort by OSHA could substantially reduce the start-up paperwork burden and costs of the HCS, particularly those of small businesses. The Small Business Administration, for example, estimated that a generic program could reduce first year program development costs by 50 percent and training costs by 25 percent, for a total first-year savings of \$700 million (2-42). A generic program could also facilitate employer compliance at the earliest possible date and improve the effectiveness of programs that are developed. Although we do not believe that the Federal Government should compete with the private market that has already developed generic hazard communication programs, we believe that a great deal can be done within the boundaries of OSHA's limited resources either to supplement the private sector or to improve the usefulness of private sector programs.

By January 1, 1988, OSHA should submit a plan, which has been developed in consultation with the U.S. Small Business Administration and the Secretary of the Department of Commerce, for an administrative effort that would provide such assistance as appropriate to alleviate the start-up paperwork burdens and costs. The

plan should include an outline of the intended approach and a timetable of actions necessary to complete the effort by the date of publication of the revised final rule and have it available to the regulated community. With the resubmission of the collection of information requirements in the final rule, OSHA should also submit a description of the plan and any documents necessary to implement it. We look forward to working with you to meet this condition of paperwork approval as efficiently and effectively as possible.

Discussion

Following is a discussion of the record and the reasons for our decisions under the Paperwork Reduction Act.¹

Multi-Employer Workplaces

The HCS relies heavily on the encyclopedic Material Safety Data Sheet (MSDS) as the primary mechanism for transmitting hazard information to employers and employees. This approach is appropriate when workers face the likelihood of significant exposure to a relatively small number of chemical hazards. Other transmittal mechanisms, however, such as generalized hazard training, are likely to be equally or more effective with much less paperwork burden when the particular hazards are continually changing or when many potentially hazardous substances are present in small quantities. In such circumstances, MSDSs have little, if any, practical utility, because neither employers nor employees can predict what, where or when exposures are likely to occur or consult the MSDS before deciding how to handle the substance. Unfortunately, these are exactly the situations where the burden of maintaining and updating MSDSs would be heaviest.

The effectiveness and efficiency of the MSDS as a source of information in various situations is disputed by a number of commenters. For example, several commenters questioned the practical utility of the provision governing multi-employer workplaces such as construction sites (1910.1200(e)(2)), which requires each employer to provide MSDSs at the workplace. The commenters stated that having the MSDS physically at the worksite would almost certainly be useless. They maintained that coordination and transfer of the MSDSs, either between employers or in a central location would be very difficult, primarily due to the numbers of employees and substances and the great frequency with which employees would arrive at and leave the site (Ex. 1-14, p. 85; 2-41; 2-48; 2-49). For example, some employees would be on-site for a few hours; others for months. Some employees would arrive directly from another worksite rather than from a central location. Other commenters (Ex. 1-14, p. 94) expressed doubt as to the need to have MSDSs actually

on the site if they were available elsewhere or if the information were available by phone or computer, an approach that the HCS permits for employees of a single employer who work at multiple locations (1910.1200(g)(9)). Similar problems were described by commenters with regard to mobile service personnel, such as repairmen, and professional launderers.

These commenters also questioned OSHA's estimates of the number of MSDSs required in multi-employer workplaces. One commenter estimated that a single industrial launderer might need to keep on file 10,000 to 50,000 MSDSs (Ex. 2-17) because delivery personnel could be exposed to different hazards at each location where they pick up or deliver laundry. The commenter estimated that the annual costs of compliance would be far higher than OSHA's estimated second-year cost of \$16 per establishment. Another commenter stated that it would not be feasible for a mobile service employee to have hard copies of MSDSs for all hazardous chemicals in the vehicle (Ex. 2-13). Several representatives of the construction industry estimated that a minimum of several file cabinets would be required on a construction site to maintain the MSDSs, and that compliance may be physically impossible (see, for example, comments by Associated General Contractors of America, 2-29; and Associated Builders and Contractors, 2-30).

In light of these objections, neither the preamble to the final rule nor the justification statement in the request for OMB paperwork review demonstrate the practical utility for the requirement to bring MSDSs on-site at multi-employer workplaces. Moreover, the requirement does not appear to be the least burdensome necessary for the efficient transmittal of hazard information in multi-employer workplaces. Hence, the requirement to bring MSDSs onto multi-employer worksites is disapproved effective May 23, 1988.

One approach that would be consistent with the Paperwork Reduction Act would be the addition of a third option to paragraph (e)(2)(i), in addition to the option of trading MSDSs between employers or depositing them in a central location. This third option would require employers at multi-employer worksites to keep labels intact on any containers they bring onto the worksite; to train their employees in the hazards with which they work directly, in recognition of and response to the general hazards that are likely to be introduced by other employers, and in the need to observe hazard labels on the worksite and request MSDSs when further information is needed; and to provide MSDSs to other employers upon request. Given the high rate of turnover in affected industries, such training should be transferable from worksite to worksite (Exs. 1-15, 2-21, 2-30).

This approach would ensure that all employees at a worksite would have access to all MSDSs upon request. This approach relies on labels and general hazard training to protect workers from substances brought onsite by other employers. It also leaves intact OSHA's existing requirement at (e)(2)(ii) that employers inform other

¹ All exhibit numbers are references to OMB paperwork docket 1218-0072, which is available to the public in Room 3201, New Executive Office Building, Washington, D.C. The prefix "1" indicates that the exhibit was received in response to the April 2, 1987, public meeting, and the prefix "2" indicates that the exhibit was received in response to the October 16, 1987, public meeting.

employers of any precautionary measures that need to be taken to protect employees, and therefore ensures that workers are protected from unusual hazards at a multi-employer worksite, as well as the normal hazards that would be included in a generalized training program.

Consumer Products

OSHA exempts from this final rule any consumer product where "the employer can demonstrate it is used in the workplace in the same manner as normal consumer use, and which use results in a duration and frequency of exposure which is not greater than exposures experienced by consumers" (1910.1200(b)(6)(vii)). This is a new exemption not contained in the existing rule, and is appropriately intended to exclude the large numbers of consumer products found in non-manufacturing workplaces. Nonetheless, this exemption is limited to consumer products that are used under certain circumstances, and hence the HCS would continue to apply to numerous consumer products present in workplaces.

The record indicates that this exemption would continue to place under the HCS large numbers of consumer products for which MSDSs would have little practical utility, and for which the burden of compliance would be substantial. We have four major concerns:

- Consumer product labeling already provides information to identify significant hazards that may result from use of the product and to enable users to avoid those hazards. For the overwhelming majority of consumer products that would remain subject to the standard, there is no evidence in the record that the MSDS would have practical utility beyond the information already included on the label.

- The exemption imposes a burden on the employer to "demonstrate" that exposures for each substance are the same as "normal consumer use," a burden that may be difficult to meet (2-44). More importantly, such a trigger would not exclude many situations where risks are very low. For example, is an employee who cleans and waxes floors once a week using a supermarket product exposed at the same duration and frequency as consumers? If not, should the employee be trained in the hazards of floor wax? Under OSHA's language, the employee may well be treated exactly like a worker on a chemical production line. In addition, the HCS requires that even consumer products that are not opened under normal workplace use, such as those a stock boy places on a supermarket shelf, be treated as "sealed containers," for which MSDSs and hazard training for potential spillage are required. This would result in treating a can of floor wax in a grocery store exactly the same as a 55-gallon drum of industrial chemical in a warehouse. In this regard, the National Retail Merchants Association stated: "It would be exceptionally difficult for retailers to adequately assess whether the hundreds of products they regularly sell could potentially become workplace hazards in the event of spillage" (Ex. 1-24, see also comments by the National Restaurant Association, 2-31).

- The exemption does not allow upstream suppliers to determine which products are

exempted, because they do not know how downstream employers will use them. Moreover, OSHA's explanation that downstream distributors who do not "generally" sell to employers would not be covered offers no relief to wholesalers and other consumer product distributors who have some accounts that are subject to the standard and others that are not. In fact upstream suppliers who want to ensure compliance will have no practical alternative but to assume that downstream employers are covered, and will therefore ship MSDSs and labels along with all consumer products. Thus, upstream suppliers will continue to bear all of the costs and the distribution/retail sector will continue to receive all of the hazard information for all consumer product. This is exactly what the consumer product exemption should be designed to avoid.

- The number of MSDSs involved is very large. Although OSHA estimated that the typical food store contained 11 chemical hazards and the largest 58, the Food Marketing Institute estimated that the typical supermarket would sell at least 1,200 nonfood consumer products that may be covered by the HCS (Ex. 2-32). The National Paint and Coatings Association calculated that paint manufacturers would be required to supply 7,000,000 MSDSs initially to retail establishments (Ex. 2-38).

We have therefore disapproved, effective May 23, 1988, coverage under the HCS of any consumer product excluded by Congress from the definition of "hazardous chemical" under Section 311(e) (3) of the Superfund Amendments and Reauthorization Act of 1986 (SARA): "Any substance to the extent it is used for personal, family or household purposes, or is present in the same form and concentration as a product packaged for distribution and use by the general public." This language would exempt any substance packaged in the same form and concentration as a consumer product whether or not it is used for the same purpose as the consumer product. EPA concluded in its final rule on Sections 311 and 312 of SARA (52 FR 38344) that this exemption is appropriate for household or consumer products in commercial and industrial as well as household use because "the public is generally familiar with such substances, their hazards and their likely locations (hence), the disclosure of such substances is unnecessary for right-to-know purposes." This alternative consumer products exemption would address the concern that the current HCS imposes unnecessary paperwork in many situations in which exposures and risks are trivial, and would reduce and simplify the paperwork requirements:

- It makes the OSHA and EPA right-to-know paperwork requirements, which are closely linked, mutually consistent. Using the same exemption in both rules avoids the situation in which employers must separate the paperwork for their "consumer products" into two groups: an OSHA "consumer product" and an EPA "consumer product."

- It establishes objective criteria that enable upstream and downstream employers to determine what is exempted and what is included. Upstream suppliers would not be forced to speculate as to the identity of the

final user (consumer or employer?) in determining whether the product is subject to the HCS. The flow of MSDSs and labels would be restricted to unpackaged substances or substances packaged for industrial or commercial use, for which detailed hazard information would be expected to have practical utility.

Drugs Regulated by FDA

The standard exempts drugs in "solid, final form for direct administration to the patient (i.e., tablets or pills)." This exemption in part avoids duplication of paperwork. Drugs for human consumption are heavily regulated by the Food and Drug Administration, which requires the transmittal of detailed information downstream from the manufacturer through professional package inserts and labels. The exemption also limits the odd situation in which a drugstore owner would be responsible for training professional pharmacists about the hazards of the drugs they dispense.

Outside the manufacturing sector, however, both rationales are equally relevant to liquid drugs not in final form. OSHA does not explain why all drugs regulated by the FDA are not exempted, except to say that North Carolina has adopted a similar exemption. Yet the paperwork burdens of covering such drugs appear to be very high. The National Wholesale Druggists Association has estimated that each drug wholesaler, with 400 pharmacy customers and 12,000 individual products covered by the HCS, would initially be required to distribute 4.8 million MSDSs (Ex. 2-24). If capsules containing solids or liquids are covered by the HCS, another 5,520 products would be added. A similar concern was raised by the Department of Agriculture (Ex. 2-50) and the Animal Health Institute (Ex. 2-40) concerning potential duplication of paperwork for veterinary biological products. Since coverage of any FDA-regulated drug would result in duplicative paperwork and is unlikely to provide additional information of any practical utility, we have disapproved coverage of FDA-regulated drugs outside the manufacturing sector, effective May 23, 1988.

Definition of "Article"

The HCS exemption of "articles" from the scope of the standard is conditionally approved through May 23, 1988. Although the record supports the need for an article exemption, the record does not support the existing definition of "article," particularly with regard to the lack of a *de minimis* exemption and the agency's interpretation of "normal conditions of use."

"Article" is defined as "a manufactured item: (i) which is formed to a specific shape or design during the manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which does not release, or otherwise result, in exposure to a hazardous chemical under normal conditions of use." OSHA explains in the preamble to the final expanded rule that "exposure" does not mean releases of "very small quantities," a "trace amount," or "a few molecules" of the hazard.

The issue raised in the record is whether an objective "de minimis" exemption should

be added to the definition of "article," perhaps similar to the quantity threshold used to define "de minimis" quantities in mixtures. OSHA exempts from the HCS substances which comprise less than one percent of a mixture (0.1 percent if the substance is a carcinogen), unless "there is evidence that the ingredient(s) could be released from the mixture in concentrations which would exceed an established OSHA permissible exposure limit (PEL) or ACGIH Threshold Limit Value (TLV), or could present a health hazard to employees" (1910.1200(g)(2)(i)(C) (1) and (2)). The one percent exclusion was included in the HCS. OSHA explained in the preamble to the 1983 final rule, "to absolve the employer from having to evaluate and list chemicals present in mixtures in small quantities, which are not likely to result in substantial exposures . . . the one percent cutoff was justified on the basis that it appeared to be protective and was considered to be reasonable by a number of affected parties" (48 FR 53290).

The record contains a number of statements that the absence of similar "de minimis" language in the definition of "article" results in the standard covering many items containing small amounts of hazardous substances and presenting low exposures to workers (one commenter noted that even the Federal Register volume in which the HCS was published emitted a measurable amount of formaldehyde, Ex. 1-25, see also Exs. 1-14, pp. 49-55; 2-36; 2-44). The lack of consistency between mixtures and articles also poses the anomalous possibility that exempt substances in a liquid or powdered mixture will become subject to the HCS when shaped or incorporated into a solid article, although the possibility of employee exposure is almost surely reduced.

The evidence is convincing that the current definition of "article" would indeed result in the inclusion of many items that present trivial risks, and that OSHA's preamble discussion of the issue is insufficient to exclude those items. It is particularly compelling that OSHA has in essence included a "de minimis" exemption for mixtures, for reasons that appear to apply equally well to manufactured items. Hence, the current "article" exemption appears to include many items under the HCS for which the paperwork requirements would have no practical utility. We therefore believe that OSHA should reconsider the definition of article. An approach more consistent with the Paperwork Reduction Act would exclude de minimis exposure expressly, and define such exposures in the same items used in the exclusion for trace components of mixtures. This approach would result in a consistent treatment of solids and chemical mixtures under the standard by exempting many items that emit small amounts of potentially hazardous substances, but not in sufficient quantities to result in significant exposures. It may also result in lower exposures by encouraging manufacturers to reduce trace element to below the threshold. The Department is instructed to complete by March 1, 1988 a rulemaking to reconsider a *de minimis* exemption in the definition of "article."

A related issue that appears to cause confusion in the regulated community is the

coverage of items such as metal or plastic pipes. These objects would appear to be "articles" since they are formed to a specific shape or design, are dependent for their end-use function on their shape or design, and would not release or otherwise result in exposure to hazardous chemicals under normal conditions of use, that is, when functioning as pipes. Yet, in a new provision exempting solid metals from labeling requirements under certain conditions, OSHA has added language that appears to suggest that such items are not "articles" if workers could be exposed to a hazard during operations such as installation or alteration of the item.

OSHA apparently intended this interpretation to address situations in which downstream employees who shape, cut, drill, or otherwise handle the solid object could be exposed to hazards, and would therefore require substance-specific hazard information about each solid object. OSHA's preamble discussion suggests that only potential exposures related to installation need be considered by the upstream supplier; the supplier does not need to consider "the possibility that exposure could occur when the item is repaired or worked on" (52 FR 31865). Nowhere does this distinction appear in the rule, however, and the question arises as to whether a practical distinction can be drawn between "installing," "working on," and "repairing."

It is difficult to understand why OSHA would consider such operations "normal conditions of use." If "normal conditions of use" apply to any possible exposure to any worker downstream, then the "article" exemption is exceedingly limited. Since manufacturers and distributors would have no way of knowing how downstream employers will treat or change the solid object, then, regardless of its hazard during its intended use, the object would be covered under the HCS, and MSDSs and labels would accompany it. The result of this interpretation would be a flood of paperwork accompanying solid objects that under normal conditions of use present no hazard at all. "Contractors will be virtually buried in MSDSs," stated the American Supply Association (Ex. 2-25).

Within the manufacturing sector, where solid objects may constitute the raw materials for extensive further processing, there may be some utility to this flow of information. Outside the manufacturing sector, however, the practical utility even in cases where such workers may be exposed seems dubious at best, and certainly has not been demonstrated in the record. Consider the case of a repairman who replaces pipe. To cut and remove existing pipe safely, he must have sufficient information and training to recognize different types of pipe and the hazards they may pose without benefit of a substance-specific MSDS or a label on the pipe. He needs no additional information to install the new pipe safely. Clearly, in these cases the repairman would benefit far more from generic hazard training on pipes than from access to substance-specific information on new pipes. In such circumstances, it is difficult to see that the practical utility is sufficient to balance the paperwork burden imposed.

The record suggests that the detailed substance-specific information provided on the MSDS can be useful in a controlled work environment, such as a manufacturing facility, in which the employer knows what hazards are present and where. Detailed substance-specific information does not, however, seem to offer much practical benefit in uncontrolled environments, such as that faced on a construction site or by a repairman, where the employer knows generally but not specifically what hazards the employee will face, or when, or where. In uncontrolled situations, generic hazard training seems much more relevant to protecting workers from the array of hazards they may face and the materials handling decisions that they must make throughout the workday.

Outside the manufacturing sector, there is likely to be little practical utility to a requirement that MSDSs and labels accompany solid objects that would be "articles" under normal conditions of use. Although one possible option would be to define all such items as "articles" exempt from the standard, there may be alternatives, such as reliance on general hazard training, that would also be consistent with an employee's need to know and the requirements of the Paperwork Reduction Act. The Department is instructed to complete by March 1, 1988, a rulemaking to reconsider its present interpretation of "normal consumer use" and fully explore these alternatives. In addition, if OSHA believes that further rulemaking is needed in specific cases to protect downstream users who handle or modify particular "articles," we look forward to assisting OSHA in developing a means for transmitting hazard information that is consistent with the Paperwork Reduction Act.

A similar concern has been expressed with regard to scrap metal, which appears to present special problems (1-22). Not only does scrap metal contain a great many substances, requiring voluminous MSDS and labels, but it also appears to pose little risk of significant exposure. We suggest that scrap metal that was classified as an "article" before it became scrap continue to fall under the "article" exemption.

Summary

In summary, the record does not demonstrate that certain paperwork requirements meet the criteria established in the Paperwork Reduction Act and its implementing regulations. Hence, we are disapproving the following paperwork requirements in the HCS, effective May 23, 1988:

- the requirement that material safety data sheets be provided on multi-employer work sites;
- coverage of any consumer product that falls within the "consumer products" exemption included in Section 311(e)(3) of the Superfund Amendments and Reauthorization Act of 1986;
- coverage of any drugs regulated by FDA in the non-manufacturing sector.

We are approving the remainder of the paperwork provisions in the HCS until May

23, 1988, on the condition that the agency complete rulemaking according to the schedule detailed earlier. The rulemaking shall consider, at least, alternatives to the definition of "article," including a *de minimis* exemption and clarification of the concept of "normal conditions of use," and shall conform the requirements on the manufacturing sector with the requirements on the non-manufacturing sector in light of this decision.

The Department shall, pursuant to 1320.13(j) and 1320.14(f), publish a notice in the *Federal Register* on the next practicable publication date to inform the public of OMB's decision under the Paperwork Reduction Act. The notice shall include the text of this letter and any other information the Department feels is necessary and appropriate.

We look forward to working with you and your staff to ensure that the collection of information provisions of the HCS meet the goal of protecting employees from hazardous exposures in a manner consistent with the requirements of the Paperwork Reduction Act.

Sincerely,

Wendy L. Gramm,

Administrator for Information and Regulatory Affairs.

cc:

Honorable John A. Pendergrass, Assistant Secretary for Occupational Safety and Health

Honorable C. William Verity, Secretary of the Department of Commerce

Honorable James Abdnor, Administrator for Small Business Administration

List of Subjects in 29 CFR 1910, 1915, 1917, 1918, 1926 and 1928

Hazard communication, Occupational safety and health, Right-to-know, Labeling, Material safety data sheets, Employee training.

Text of Amendment

Following the text of §§ 1910.1200, 1915.99, 1917.28, 1918.90 and 1926.59 of Title 29 of the Code of Federal Regulations add:

(Approved by the Office of Management and Budget under Control No. 1218-0072)

Signed at Washington, DC, this 30th day of November 1987.

John A. Pendergrass,

Assistant Secretary for Occupational Safety and Health.

[FR Doc. 87-27891 Filed 12-3-87; 8:45 am]

BILLING CODE 4510-26-M

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; Amendment

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Under Secretary of the Navy has determined that USS INGERSOLL (DD-990) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with its special function as a naval destroyer. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: November 18, 1987.

FOR FURTHER INFORMATION CONTACT: Captain P.C. Turner, JAGC, U.S. Navy Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332-2400, Telephone number: (202) 325-9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C.

1605, the Department of the Navy amends 32 CFR Part 706. This amendment provides notice that the Under Secretary of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS INGERSOLL (DD-990) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with 72 COLREGS, Annex I, section 3(a), pertaining to the location of the forward masthead light in the forward quarter of the vessel, the placement of the after masthead light, and the horizontal distance between the forward and after masthead lights, without interfering with its special functions as a naval destroyer. The Under Secretary of the Navy has also certified that the aforementioned lights are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR Parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine Safety, Navigation (Water), Vessels.

Accordingly, 32 CFR Part 706 is amended as follows:

PART 706—[AMENDED]

1. The authority citation for 32 CFR Part 706 continues to read:

Authority: 33 U.S.C. 1605.

§ 706.2 [Amended]

2. Table Five of § 706.2 is amended by adding the following vessel:

Vessel	Number	Forward masthead light less than the required height above hull. Annex I, sec. 2(a)(i)	Aft masthead light less than 4.5 meters above forward masthead light. Annex I, sec. 2(a)(ii)	Masthead lights not over all other lights and obstructions. Annex I, sec. 2(f)	Vertical separation of masthead lights used when towing less than required by Annex I, sec. 2(a)(i)	Aft masthead lights not visible over forward light 1,000 meters ahead of ship in all normal degrees of trim. Annex I, sec. 2(b)	Forward masthead light not in forward quarter of ship. Annex I, sec. 3(a)	After masthead light less than 1/2 ship's length aft of forward masthead light. Annex I, sec. (3)(a)	Percentage horizontal separation attained.
USS INGERSOLL	DD-990						X	X	46

Date: November 18, 1987.

Approved.

H. Lawrence Garrett, III,

Under Secretary of the Navy.

[FR Doc. 87-27820 Filed 12-3-87; 8:45 am]

BILLING CODE 3810-AE-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD5-87-032]

Drawbridge Operation Regulations; Beaufort Channel, Beaufort, NC

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: At the request of the North Carolina Department of Transportation, the Coast Guard is changing the regulations governing the operation of the drawbridge on U.S. 70 across Beaufort Channel, mile 0.1, at Beaufort, North Carolina. This change is being made in an effort to alleviate highway traffic congestion in the vicinity of the drawbridge. Since this action does not reduce the number of possible draw openings, it should provide for the reasonable needs of navigation.

EFFECTIVE DATE: These regulations become effective on January 4, 1988.

FOR FURTHER INFORMATION CONTACT: Ann B. Deaton, Bridge Administrator, telephone (804) 398-6222.

SUPPLEMENTARY INFORMATION: On June 18, 1987, the Coast Guard published proposed rules (52 FR 23187) concerning this amendment. The Commander, Fifth Coast Guard District, also published the proposal as a Public Notice dated June 18, 1987. In each notice interested persons were given until August 28, 1987, to submit comments.

Drafting Information

The drafters of these regulations are Linda L. Gilliam, Project Officer, and CDR Robert J. Reining, Project Attorney.

Discussion of Comments

In February 1987, the North Carolina Department of Transportation requested a change in the drawbridge regulations governing the operation of the bridge on U.S. 70 across Beaufort Channel, mile 0.1, at Beaufort, North Carolina, to restrict the openings of the bridge between 7:30 a.m. and 7:30 p.m. from May 1 through October 31. Restriction currently apply to the period between 7:00 a.m. and 7:00 p.m.

A proposed rule was published in the Federal Register (52 FR 23187) on June

18, 1987. As a result of the notice of proposed rulemaking, three letters were received. All of the responses favored the proposed changes to the regulations.

Economic Assessment and Certification

These regulations are considered to be non-major under Executive Order 12291 on Federal Regulation and nonsignificant under Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979). The economic impact has been found to be so minimal that a full regulatory evaluation is unnecessary. This conclusion is based on the fact that the proposed regulation will have no effect on commercial navigation, or on any industries that depend on waterborne transportation. Since the economic impact of these regulations is expected to be minimal, the Coast Guard certifies that they will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

In consideration of the foregoing, Part 117 of Title 33, Code of Federal Regulations, is amended as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for Part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05-01(g).

2. Section 117.822 is revised to read as follows:

§ 117.822 Beaufort Channel, North Carolina

(a) From May 1 to October 31, the draw shall open on signal every hour on the half hour from 7:30 a.m. to 7:30 p.m. for the passage of pleasure craft. To accommodate approaching pleasure craft, the hourly opening may be delayed up to 10 minutes past the half hour.

(b) The draw shall open on signal for public vessels of the United States, state and local governments, commercial vessels, and any vessel in an emergency involving danger to life or property.

Dated: November 19, 1987.

A.D. Breed,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 87-27817 Filed 12-3-87; 8:45 am]

BILLING CODE 4910-14-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[FRL-3298-2]

Designation of Areas for Air Quality Planning Purposes; Pennsylvania; Redesignation of Portions of the Johnstown Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a request from the Commonwealth of Pennsylvania to redesignate several portions of the Johnstown, Pennsylvania area to "Better Than National Standards" with respect to Total Suspended Particulates (TSP).

EFFECTIVE DATE: This rule will become effective on January 4, 1988.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the following locations:

U.S. Environmental Protection Agency, Region III, Air Management Division, 841 Chestnut Building, Philadelphia, PA 19107, Attn: Esther Steinberg
Commonwealth of Pennsylvania, Department of Environmental Resources, Bureau of Air Quality Control, 200 North 3rd Street, Harrisburg, PA 17120, Attn: Gary Triplett.

FOR FURTHER INFORMATION CONTACT: Larry Budney at the EPA Region III address stated above or telephone (215) 597-0545.

SUPPLEMENTARY INFORMATION: Under section 107(d) of the Clean Air Act (Act) the Administrator of EPA has promulgated the National Ambient Air Quality Standards (NAAQS) attainment status for all areas within each State (see 43 FR 8962 (March 3, 1978)). These area designations are subject to revision whenever sufficient data become available to warrant a redesignation.

The Pennsylvania Department of Environmental Resources (DER) has submitted to the U.S. Environmental Protection Agency (EPA), on July 1, 1985 a request to have the following portions of the Johnstown area redesignated with respect to TSP:

City of Johnstown and Dale Borough (Boro) redesignated from "Does Not Meet Secondary Standards" to "Better Than National Standards."
East Conemaugh Boro and Franklin Boro redesignated from "Does Not Meet

Primary Standards" to "Better Than National Standards."

East Taylor Township (Twp.), Middle Taylor Twp. and West Taylor Twp. redesignated from "Cannot Be Classified" to "Better Than National Standards."

The air quality data from January 1983 through the end of 1986 indicate that the Johnstown area shows no violations of the TSP air quality standards and therefore, EPA is redesignating this area to attainment for TSP.

EPA has examined the air quality data collected from the monitoring sites used to demonstrate attainment and found that the data were collected in accordance with all EPA requirements. In addition, DER has provided evidence of an implemented control strategy and evidence that emissions are not likely to increase in this area. There are no stacks in excess of Good Engineering Practice (GEP) in the area and no dispersive techniques have been implemented.

The improvement in air quality was accompanied by a reduction in actual and allowable emissions of 980 tons per year. This was due to the permanent shutdown of Bethlehem Steel's coke battery and blast furnace. This facility would need a new source review permit to recommence operation.

In the January 20, 1987 Proposed Rule (52 FR 2118) concerning this action, EPA

inadvertently proposed that East Conemaugh Boro and Franklin Boro be reclassified from secondary nonattainment to attainment, but should have proposed reclassification from primary nonattainment to attainment. That happened as a result of the fact that in a previous letter from the Commonwealth dated July 27, 1984, it was requested that the designation for those boros be changed from primary nonattainment to secondary nonattainment. That request was proposed in the **Federal Register** on March 11, 1985 (50 FR 9694), and no comments were received. Final action was not taken due to the lack of support documentation necessary to reclassify those areas. However, in the request that is the subject of today's action, the necessary documentation was provided to demonstrate full attainment for those areas. Since no comments were received during the comment period for either of the proposed actions, EPA does not consider it to be necessary to repropose this reclassification action.

Final Action

EPA is approving the July 1, 1985 request from the Commonwealth of Pennsylvania to redesignate certain portions of the Johnstown area to attainment for TSP.

The Office of Management and Budget has exempted this rule from the

requirements of section 3 of Executive Order 12291.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by (60 days from date of publication). This action may not be challenged later in proceedings to enforce its requirements (See section 307(b)(2)).

List of Subjects in 40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

Dated: November 20, 1987.

Lee M. Thomas,
Administrator.

Part 81 of Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 81—[AMENDED]

Subpart NN—Pennsylvania

1. The authority citation for Part 81 continues to read as follows:

Authority: 42 U.S.C. 7401-7642.

2. Section 81.339 is amended by revising entry IV.(A) for the "Johnstown Air Basin" in the table for Total Suspended Particulates to read as follows:

§ 81.339 Pennsylvania.

PENNSYLVANIA—TSP

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standards
IV. Central Pennsylvania Intrastate AQCR:				
(A) Johnstown Air Basin: Cambria County:				
City of Johnstown.....				X
Dale Boro.....				X
East Conemaugh Boro.....				X
Franklin Boro.....				X
East Taylor Twp.....				X
Middle Taylor Twp.....				X
West Taylor Twp.....				X

[FR Doc. 87-27865 Filed 12-3-87; 8:45 am]

BILLING CODE 6560-50-M

VETERANS ADMINISTRATION

48 CFR Part 819

Acquisition Regulations for Small Business Concerns

AGENCY: Veterans Administration.

ACTION: Final regulation.

SUMMARY: The Veterans Administration (VA) is revising the VA Acquisition Regulation (VAAR) to address the procedure for processing Small Business Administration Certificate of Competency appeals and to include additional language to increase the emphasis on giving Vietnam era and disabled veteran-owned firms every

opportunity to participate in selling items and services to the VA.

EFFECTIVE DATE: November 24, 1987.

FOR FURTHER INFORMATION CONTACT: Chris A. Figg, Policy and Interagency Service (91A), Office of Procurement and Supply, Veterans Administration 810 Vermont Avenue NW., Washington, DC 20420, (202) 233-2334.

SUPPLEMENTARY INFORMATION:

I. Background

On May 4, 1987, there was published in the Federal Register (52 FR 18290) a notice of proposed rulemaking providing internal procedures for processing Small Business Administration Certificate of Competency appeals and providing additional language to give the Vietnam era and disabled veteran-owned firms every opportunity to participate in VA procurement opportunities.

Interested persons were given 30 days to comment on the proposal. The VA received no comments in response to the notice of proposed rulemaking; therefore, the regulation is adopted.

II. Executive Order 12291

Pursuant to the memorandum from the Director, Office of Management and Budget, to the Administrator, Office of Information and Regulatory Affairs, dated December 13, 1984, this final rule is exempt from sections 3 and 4 of Executive Order 12291.

III. Regulatory Flexibility Act (RFA)

Because this proposed rule does not come within the term "rule" as defined in the RFA (5 U.S.C. 601(2)), it is not subject to the requirements of that Act. In any case, this change will not have a significant impact on a substantial number of small entities because the provisions implement the requirements of the Competition in Contracting Act (CICA) as required by the Federal Acquisition Regulation (FAR). The provisions are primarily internal procedures which will not impact the private sector.

IV. Paperwork Reduction Act

This proposed rule requires no additional information collection or recordkeeping requirements upon the public.

List of Subjects in 48 CFR Part 8

Government procurement.

Approved: November 24, 1987.

Thomas K. Turnage,
Administrator.

Part 819 of title 48 of the Code of Federal Regulations is amended as follows:

PART 819—SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS CONCERNS

1. The authority citation for Part 819 continues to read as follows:

Authority: 38 U.S.C. 210 and 40 U.S.C. 486(c).

2. Subpart 819.6 is added to read as follows:

Subpart 819.6 Certificates of Competency and Determinations of Eligibility

819.602-3 Appealing Small Business Administration's decision to issue Certificates of Competency.

Formal VA appeals of an initial concurrence by the SBA Central Office in an SBA Regional Office decision to issue a Certificate of Competency (CoC) will be processed as follows:

(a) When the contracting officer believes that the VA should formally appeal the concurrence by the SBA Central Office in an SBA Regional Office decision to issue a CoC, the contracting officer will so notify the Director, Office of Procurement and Supply (93B) in writing within five business days after receipt of the SBA Central Office's written confirmation of its determination. Within ten business days of the contracting officer's receipt of the SBA's written confirmation (or within a period acceptable to the VA and the SBA), the Director, Office of Procurement and Supply (93B) will advise the SBA Central Office that the VA intends to file a formal appeal.

(b) Within ten business days of the contracting officer's receipt of the SBA Central Office's written confirmation, the contracting officer will furnish an original and one copy of the appeal file to the Director, Office of Procurement and Supply (93B). The file must contain a copy of the bid/offer from the firm considered nonresponsive, a copy of the bid/offer from the firm otherwise in line for award, a copy of the bid, a copy of the bid abstract, a copy of SBA's CoC Review Committee report, a copy of all correspondence with SBA on the matter, and the contracting officer's narrative statement establishing the error, omission, or other basis for disputing SBA's proposed responsibility determination.

(c) The Director, Office of Procurement and Supply (93B) will review the file prepared by the contracting officer. If the contracting officer's position is accepted, the Director, Office of Procurement and Supply (93B) will transmit the formal appeal to the SBA Central Office within ten business days after notifying that office of the VA's intent to appeal (or within a period acceptable to the VA and the SBA). The contracting officer will be informed of the final SBA decision.

(d) If, after the Central Office review, it is decided that a formal appeal should not be made to the SBA, the contracting officer will be advised of this decision and that the CoC should be accepted by the VA. The SBA Central Office will

also be advised that the VA will not pursue its formal appeal. If the decision concerns major construction projects and the Office of Facilities disagrees with the decision made by the Director, Office of Procurement and Supply, the matter will be referred to the Senior Procurement Executive for a final VA determination.

3. In section 819.807-70, the heading and first sentence are revised to read as follows:

819.807-70 Commitments of the Office of Facilities' funded projects for the 8(a) program.

Major and minor projects funded by the Office of Facilities (including those delegated to the Department of Medicine and Surgery) which have been committed to the 8(a) program will not be withdrawn from that program without the consent of the Office of Small and Disadvantaged Business Utilization (005C). * * *

4. In section 819.7004, the heading and first sentence is revised to read as follows:

819.7004 Waiver of the use of Vietnam era or disabled veteran-owned firms.

It is the policy of the VA to provide Vietnam era and disabled veteran-owned firms every opportunity to participate in the acquisition process.
* * *

[FR Doc. 87-27775 Filed 12-3-87; 8:45 am]

BILLING CODE 8320-01-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Removal of *Gambusia amistadensis*, the Amistad *Gambusia*, From the List of Endangered and Threatened Wildlife

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The U.S. Fish and Wildlife Service is removing the Amistad gambusia (*Gambusia amistadensis*) from the List of Endangered and Threatened Wildlife. This action is based on a review of all available data, which indicate that this fish is extinct. The species is known to have occurred naturally only in Goodenough Spring, Val Verde County, Texas. It was eliminated there by inundation from the Amistad Reservoir, an impoundment constructed on the Rio Grande River in

1968. All other springs considered likely to harbor the species have been examined, but it was never found. Captive populations of *G. amistadensis* were maintained, but have since died or been eliminated through hybridizations with and predation by the mosquitofish (*Gambusia affinis*). Removing the Amistad gambusia from the List constitutes Service recognition of its extinction and removes Federal protection under the Endangered Species Act.

DATE: This rule becomes effective on January 4, 1988.

ADDRESSES: The complete file for this rule is available for inspection, by appointment, during normal business hours at the Service's Regional Office of Endangered Species, 500 Gold Avenue SW., Room 4000, Albuquerque, New Mexico.

FOR FURTHER INFORMATION CONTACT: Gerald L. Burton, Endangered Species Biologist, U.S. Fish and Wildlife Service, P.O. Box 1306, Albuquerque, New Mexico 87103 (505/766-3972 or FTS 474-3972).

SUPPLEMENTARY INFORMATION:

Background

The Amistad (Goodenough) gambusia (*Gambusia amistadensis*) is known to have occurred only in Goodenough Spring, a tributary of the Rio Grande in Val Verde County, Texas. It was described by Dr. Alex Peden in 1973, based on specimens collected in 1968 from Goodenough Spring just prior to its inundation by Amistad Reservoir. The species was not recognized as distinct until well after reservoir construction began (Peden 1973). During extensive collecting by Peden (1973) in spring areas immediately upstream and downstream from the Amistad Reservoir, no additional *G. amistadensis* were found, and Peden believed that the species was restricted to the Goodenough Spring area.

In July 1968, backwaters of the Amistad Reservoir, constructed by the U.S. Army Corps of Engineers, began permanent flooding of the area. In subsequent visits to the area after the reservoir had filled, the spring was found to be under more than 21.3 meters (70 feet) of silt-laden water, and Peden (1973) believed that the species was probably extirpated there. In 1979, all Texas springs listed by Brune (1981) as being within 50 kilometers (31 miles) of Goodenough Spring with outflow in excess of 10 liters per second (0.353 cubic feet per second) were surveyed, but no *G. amistadensis* were found, and the species is believed to be extinct (Hubbs and Jensen 1984).

Gambusia amistadensis was listed as endangered on April 30, 1980 (45 FR 28721), under provisions of the Endangered Species Act of 1973, as amended, at which time it occurred only in captivity at the University of Texas and Dexter National Fish Hatchery in New Mexico. Since that time, all captive populations have died or been eliminated through hybridization with and predation by the mosquitofish, *Gambusia affinis*. In the Federal Register of March 11, 1987 (52 FR 7462-7463), the Service published a proposed rule to delist the Amistad gambusia.

Summary of Comments and Recommendations

In the March 11, 1987, proposed rule (52 FR 7462) and associated notifications, all interested parties were requested to submit information that might contribute to the development of a final rule. Appropriate State agencies, county governments, Federal agencies, scientific organizations, and other interested parties were contacted and requested to comment. A newspaper notice that invited general public comment was published in the *Del Rio News-Herald* on April 3, 1987. Five comments were received and are discussed below.

Comments of support were received from the Texas Parks and Wildlife Department, the American Society of Ichthyologists and Herpetologists, a faculty member from the University of Texas at Austin, and a faculty member from Pan American University. A letter of opposition was received from a faculty member from the University of Oklahoma.

The commenter from the University of Oklahoma stated that he could see no benefit to delisting because of presumed extinction, and if the species remains on the list, it will automatically have protection if any other populations are discovered. The Service responds that maintaining a species on the List when it is presumed extinct causes an unnecessary burden on Federal Agencies when they evaluate projects in the context of section 7 of the Endangered Species Act. In addition, if the species is rediscovered, it can be relisted expeditiously under emergency provisions of the Act.

Summary of Status Findings

After a careful review of all available data, the Service has determined that *Gambusia amistadensis* is extinct and no longer requires protection pursuant to the Endangered Species Act of 1973, as amended. If evidence to the contrary is presented later, listing may be repropose.

Regulations at 50 CFR 424.11 state that a species may be delisted if: (1) It becomes extinct, (2) it recovers, or (3) the original classification data were in error. The Service believes that enough evidence exists to recognize *Gambusia amistadensis* as extinct. The Endangered Species Act requires that certain factors be considered before a species can be listed, reclassified, or delisted. These factors and their application to *G. amistadensis* are as follows:

A. The present or threatened destruction, modification or curtailment of its habitat or range. The Amistad gambusia was known to occur only in Goodenough Spring, tributary to the Rio Grande in Val Verde County, Texas. In July of 1968, backwaters of the Amistad Reservoir began permanent flooding of the area. The Amistad gambusia is believed to have been extirpated in that area.

B. Overutilization for commercial, recreational, scientific, or educational purposes. Not applicable.

C. Disease or predation. Not applicable.

D. The inadequacy of existing regulatory mechanisms. Not applicable.

E. Other natural or manmade factors affecting its continued existence. All captive populations of *G. amistadensis* have died or been eliminated due to hybridization with and predation by the mosquitofish (*Gambusia affinis*).

Effects of Rule

This action removes this species from the List of Endangered and Threatened Wildlife. Federal agencies are no longer required to consult with the Secretary to insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of the Amistad gambusia. Federal restrictions on taking this species no longer apply. There is no designated critical habitat for this species.

National Environmental Policy Act

The Fish and Wildlife Service has determined that an Environmental Assessment, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. A notice outlining the Service's reasons for this determination was published in the Federal Register on October 25, 1983 (48 FR 49244).

References Cited

- Brune, G. 1981. Springs of Texas, 1. Branch-Smith, Inc. Ft. Worth, Texas.
- Hubbs, C. and B.L. Jensen. 1984. Extinction of *Gambusia amistadensis*, an endangered fish. *Copeia* 1984(2):529-530.
- Peden, A.E. 1973. Virtual extinction of *Gambusia amistadensis* n. sp., a poeciliid fish from Texas. *Copeia* 1973(2):210-221.

Primary Author

The primary author of this final rule is Alisa M. Shull, Endangered Species Biologist, U.S. Fish and Wildlife Service, Albuquerque, New Mexico 87103 (505/766-3972 or FTS 474-3972).

List of Subjects in 50 CFR Part 17

Endangered and threatened wildlife, Fish, Marine mammals, Plants (agriculture).

Regulation Promulgation

Accordingly, Part 17, Subchapter B of Chapter I, Title 50 of the Code of Federal Regulations, is amended as set forth below:

PART 17—[AMENDED]

1. The authority citation for Part 17 continues to read as follows:

Authority: Pub. L. 93-205, 87 Stat. 884; Pub. L. 94-359, 90 Stat. 911; Pub. L. 95-632, 92 Stat. 3751; Pub. L. 96-159, 93 Stat. 1225; Pub. L. 97-304, 96 Stat. 1411 (16 U.S.C. 1531 *et seq.*); Pub. L. 99-625, 100 Stat. 3500 (1986), unless otherwise noted.

§ 17.11 [Amended]

2. Amend § 17.11(h) by removing *Amistad gambusia* (*Gambusia amistadensis*) under "Fishes" from the List of Endangered and Threatened Wildlife.

Dated: October 22, 1987.

Susan Recce,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 87-27912 Filed 12-3-87; 8:45 am]

BILLING CODE 4310-55-M

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Determination of Endangered Status for *Crescentia portoricensis*

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The Service determines endangered status for a plant, *Crescentia portoricensis* (Higuero de Sierra), pursuant to the Endangered Species Act (Act) of 1973, as amended. *Crescentia portoricensis* is endemic to evergreen, semievergreen, and

deciduous forests on serpentine in the lower Cordillera region of southwestern Puerto Rico. This small tree is threatened by the indirect effects of deforestation and its extremely low population size. This rule implements the Federal protection and recovery provisions afforded by the Act for *Crescentia portoricensis*.

DATES: The effective date of this rule is January 4, 1988.

ADDRESSES: The complete file for this rule is available for inspection, by appointment, during normal business hours at the Caribbean Field Office, U.S. Fish and Wildlife Service, P.O. Box 491, Boqueron, Puerto Rico 00622, and at the Service's Southeast Regional Office, Suite 1282, 75 Spring Street SW., Atlanta, Georgia 30303.

FOR FURTHER INFORMATION CONTACT: Ms. Susan Sealander at the Caribbean Field Office address (809/851-7297) or Mr. Richard P. Ingram at the Atlanta Regional Office address (404/331-3583 or FTS 242-3583).

SUPPLEMENTARY INFORMATION:

Background

Crescentia portoricensis was discovered by N. L. Britton in 1913 along the Maricao River in western Puerto Rico. A small population of the species was later found approximately 10 miles (16 kilometers) to the southwest in the Susua area. Prior to 1979, the species was known from two small populations in Maricao Commonwealth Forest and a third in Susua Commonwealth Forest, each population consisting of about six plants. The two Maricao populations were not found during a 1979 survey (Vivaldi and Woodbury 1981), and repeated searches of these sites have failed to locate the plants. However, five populations with 36 individuals were recently discovered in the Maricao area by Commonwealth Forest personnel. Thus, a total of 42 plants are now known from six sites.

Crescentia portoricensis is an evergreen vinelike shrub or small tree reaching 20 feet (6 meters) in height, with a trunk diameter of 3 inches (8 centimeters). The leaves are simple, oblanceolate to narrowly elliptic, shiny dark green and leathery, and usually clustered at the nodes. The yellowish-white flowers are tubular and irregularly bell-shaped. The fruits are cylindric, hard, and dry. The species is endemic to the montane and lower montane mixed evergreen, semievergreen, and deciduous forests of the lower Cordillera of southwest Puerto Rico. Much of this region is underlain by serpentine, which appears as outcrops or serpentinite soils, and contributes to a high floristic

diversity and endemism. Within the two Commonwealth Forest units where it occurs, *Crescentia portoricensis* is restricted to sites along permanent or intermittent watercourses.

Deforestation has had a significant effect on the native flora of Puerto Rico, particularly at lower elevations. The lands presently within Susua Commonwealth Forest, entirely below 1,550 feet (475 meters), were deforested by the beginning of this century. The fact that *Crescentia portoricensis* occupied sites in ravine-bottoms probably contributed to its persistence in this area, although such sites were then exposed to the after-effects of deforestation. The lands at higher elevations (up to 2,880 feet or 875 meters) in Maricao Commonwealth Forest have largely escaped such extreme alternation, but both Maricao and Susua have continued to be affected indirectly by deforestation of adjacent lands and the increased incidence of erosion, landslides, and flash flooding. Since it occupies stream and valley bottom habitats, *Crescentia portoricensis* has been particularly vulnerable to these impacts. It is believed that the two previously known Maricao populations were lost to flooding and the resulting erosion of their habitat.

Crescentia portoricensis was recommended for Federal listing by the Smithsonian Institution (Ayensu and DeFilipps 1978). The species was included among the plants being considered as endangered or threatened species by the Fish and Wildlife Service, as identified in the notice published in the December 15, 1980, *Federal Register* (45 FR 82480). The species was placed in category 1 (species for which the Service has substantial information supporting the appropriateness of proposing to list them as endangered or threatened), and was retained in category 1 in the September 27, 1985, revised notice (50 FR 39526).

In a notice published in the *Federal Register* on February 15, 1983 (48 FR 6752), the Service reported the earlier acceptance of the new taxa in the Smithsonian's 1978 book as under petition within the context of section 4(b)(3)(A) of the Act, as amended in 1982. The Service subsequently found on October 13, 1983, October 12, 1984, October 11, 1985, and October 10, 1986, that listing *Crescentia portoricensis* was warranted but precluded by other pending listing actions, in accordance with section 4(b)(3)(B)(iii) of the Act. The Service proposed listing *Crescentia portoricensis* on January 14, 1987.

Summary of Comments and Recommendations

In the January 14, 1987, proposed rule and associated notifications, all interested parties were requested to submit factual reports or information that might contribute to the development of a final rule. Appropriate agencies of the Commonwealth of Puerto Rico, Federal agencies, scientific organizations, and other interested parties were contacted and requested to comment. A newspaper notice inviting general public comment was published in the *San Juan Star* on February 6, 1987. Six letters of comment were received and are discussed below. A public hearing was neither requested nor held.

The Secretary of the Puerto Rico Department of Natural Resources supported the proposed listing of *Crescentia portoricensis*. The Federal Highway Administration, U.S. Forest Service, and Environmental Protection Agency each acknowledged the proposal and stated that no specific actions under consideration by their agencies would affect the species. The Natural History Society of Puerto Rico indicated no objection to the proposal but also noted that *Crescentia portoricensis* might occur on the Cabo Rojo National Wildlife Refuge. The Service can find no record of such occurrence, and considers that this suggestion may refer to another species of *Crescentia*. The U.S. Army Corps of Engineers responded with a request for more information; this request was answered, and the Corps elected not to comment on the proposal at this time.

Summary of Factors Affecting the Species

After a thorough review and consideration of all information available, the Service has determined that *Crescentia portoricensis* should be classified as an endangered species. Procedures found at section 4(a)(1) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and regulations (50 CFR Part 424) promulgated to implement the listing provisions of the Act were followed. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1). These factors and their application to *Crescentia portoricensis* Britton (Higüero de Sierra) are as follows:

A. The present or threatened destruction, modification, or curtailment of its habitat or range. The indirect effects of deforestation, particularly habitat modification and direct destruction of plants through erosion or landslides caused by accelerated runoff

and flash flooding, appear to be the most serious threats to *Crescentia portoricensis*. Although the surviving populations exist within units of the Commonwealth Forest system, the alteration of surrounding lands continues to affect the species and its habitat. In addition, flood control projects, which include large reservoirs in the mountains of the Maricao area, have been proposed by the Army Corps of Engineers. If these are constructed, impoundments could extend into drainages where the species may occur.

B. Overutilization for commercial, recreational, scientific, or educational purposes. Taking for these purposes has not been a documented factor in the decline of this species, but could become so in the future. Species of the genus *Crescentia* (calabash) are widely cultivated throughout the Old and New World tropics. Overcollection could prove a serious problem for this species, since only 42 individuals are known to exist in the wild.

C. Disease or predation. Disease and predation have not been documented as factors in the decline of this species.

D. The inadequacy of existing regulatory mechanisms. The Commonwealth of Puerto Rico has recently adopted a regulation that recognizes and provides protection for certain Commonwealth listed species. However, *Crescentia portoricensis* is not yet on the Commonwealth list. Federal listing would provide the Act's recovery and protection provisions to this small tree.

E. Other natural or manmade factors affecting its continued existence. The known populations of *Crescentia portoricensis* are confined to geographically small areas and thus are susceptible to a variety of natural disturbances, such as major storms and resulting landslides or flooding. Although the species is probably adapted to survive such events, these natural threats are exacerbated by the manmade conditions outlined in factor "A" above. In addition, with only 42 plants known to exist, and no seedlings ever observed, rarity is itself a factor affecting continued survival.

The Service has carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this species in determining to make this rule final. Based on this evaluation, the preferred action is to list *Crescentia portoricensis* as endangered. Since there are few individuals remaining and a continuing risk of damage to the plants and/or their habitat, endangered status seems an accurate assessment of the

species' condition. It is not prudent to designate critical habitat because of the reasons given below.

Critical Habitat

Section 4(a)(3) of the Act, as amended, requires that to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time a species is determined to be endangered or threatened. The Service finds that designation of critical habitat is not prudent for *Crescentia portoricensis* at this time. The distribution of this species is so restricted that collecting or vandalism could seriously damage or eliminate the remaining populations. Publication of critical habitat descriptions and maps in the *Federal Register* would increase the likelihood of such activities. Federal involvement in the areas where this plant occurs can be identified without the designation of critical habitat. All involved parties and landowners will be notified of the location and importance of protecting this species' habitat, and such protection will be addressed through the recovery process and through section 7 procedures (see "Available Conservation Measures," below).

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Endangered Species Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in conservation action by Federal, Commonwealth, and private agencies, groups, and individuals. The Endangered Species Act provides for possible land acquisition and cooperation with the Commonwealth and requires that recovery actions be carried out for all listed species. Such actions are initiated by the Service following listing. The protection required of Federal agencies and the prohibitions against taking are discussed, in part, below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR Part 402. Section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of a listed species or to

destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service. No critical habitat is being proposed for *Crescentia portoricensis*, as discussed above. Federal involvement is expected only if flood control projects are begun by the U.S. Army Corps of Engineers. However, through careful planning, adverse impacts to this species can be minimized.

Section 9(a)(2) of the Act and its implementing regulations found at 50 CFR 17.61, 17.62, and 17.63 set forth a series of general trade prohibitions and exceptions that apply to all endangered plants. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export any endangered plant, transport it in interstate or foreign commerce in the course of commercial activity, sell or offer it for sale in interstate for foreign commerce, or remove it from areas under Federal jurisdiction and reduce it to possession. Certain exceptions can apply to agents of the Service and Commonwealth conservation agencies. The Act and 50 CFR 17.62 and 17.63 also provide for the issuance of permits to carry out otherwise prohibited activities involving endangered plant species under certain circumstances. Although there may be

some horticultural interest in *Crescentia portoricensis*, it is anticipated that few trade permits would ever be sought or issued since the species is not known to be in cultivation and is uncommon in the wild. Requests for copies of the regulations on plants and inquiries regarding them may be addressed to the Federal Wildlife Permit Office, U.S. Fish and Wildlife Service, Washington, DC 20240 (703/235-1903).

National Environmental Policy Act

The Fish and Wildlife Service has determined that an Environmental Assessment, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. A notice outlining the reasons for this determination was published in the *Federal Register* on October 25, 1983 (48 FR 49244).

References Cited

- Ayensu, E.S., and R.A. DeFilipps. 1978. *Endangered and Threatened Plants of the United States*. Smithsonian Institution and World Wildlife Fund, Washington, DC, xv + 403 pp.
- Vivaldi, J.L., and R.O. Woodbury. 1981. Status report on *Crescentia portoricensis* Britton. Unpublished status report submitted to the U.S. Fish and Wildlife Service, Atlanta, 28 pp.

Author

The primary author of this final rule is Mr. David Densmore, Caribbean Field Office, U.S. Fish and Wildlife Service, P.O. Box 491, Boqueron, Puerto Rico 00622 (809/851-7297).

List of Subjects in 50 CFR Part 17

Endangered and threatened wildlife, Fish, Marine mammals, Plants (agriculture).

Regulation Promulgation

Accordingly, Part 17, Subchapter B of Chapter I, Title 50 of the Code of Federal Regulations, is amended as set forth below:

PART 17—[AMENDED]

1. The authority citation for Part 17 continues to read as follows:

Authority: Pub. L. 93-205, 87 Stat. 884; Pub. L. 94-359, 90 Stat. 911; Pub. L. 95-632, 92 Stat. 3751; Pub. L. 96-159, 93 Stat. 1225; Pub. L. 97-304, 96 Stat. 1411 (16 U.S.C. 1531 *et seq.*); Pub. L. 99-625, 100 Stat. 3500 (1986), unless otherwise noted.

2. Amended § 17.12(h) by adding the following, in alphabetical order under Bignoniaceae, to the List of Endangered and Threatened Plants:

§ 17.12 Endangered and threatened plants:

* * * * *

(h) * * *

Species		Historic range	Status	When listed	Critical habitat	Special rules
Scientific name	Common name					
Bignoniaceae—Bignonia family:						
<i>Crescentia portoricensis</i>	Higuero de Sierra	U.S.A. (PR)	E	301	NA	NA

Dated: October 22, 1987.

Susan Recce,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 87-27913 Filed 12-3-87; 8:45 am]

BILLING CODE 4310-55-M

50 CFR Part 20

Migratory Bird Hunting; Late Seasons, and Bag and Possession Limits for Certain Migratory Game Birds in the United States

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule amendment.

SUMMARY: This final rule amendment prescribes the daily bag and possession limits for ducks in the Mississippi

Flyway in those States selecting the point system. These bag limits were omitted from the rulemaking dated Tuesday, September 29, 1987 (52 FR 36496).

EFFECTIVE DATE: December 4, 1987.

FOR FURTHER INFORMATION CONTACT: Rollin D. Sparrowe, Chief, Office of Migratory Bird Management, Matomic Building—Room 536, U.S. Fish and Wildlife Service, Department of the Interior, Washington, DC 20240 (202/254-3207).

SUPPLEMENTARY INFORMATION: On September 29, 1987, the U.S. Fish and Wildlife Service (hereinafter the Service) published in the *Federal Register* (52 FR 36496) a final rule prescribing the late open seasons, hunting hours, hunting areas, and daily bag and possession limits for general

1987-88 waterfowl seasons in the conterminous United States. In a table on page 36519 of that rulemaking, the Service prescribed the point values assigned to the species and sexes of ducks for States in the Mississippi Flyway that select the point system, but inadvertently omitted prescribing the daily bag and possession limits. The addition of the daily bag and possession limits to that table is made in this final rule amendment.

Environmental Considerations

Compliance of the 1987-88 migratory game bird hunting regulations with the National Environmental Policy Act and the Endangered Species Act were addressed by the Service in the September 29, 1987, "final" rule.

Regulatory Flexibility Act, Executive Order 12291 and Paperwork Reduction Act

In the March 13, 1987, *Federal Register* (52 FR 7900), the Service reported measures it had undertaken to comply with requirements of the Regulatory Flexibility Act and the Executive Order. The annual migratory game bird hunting regulations contain no information collections subject to Office of Management and Budget review under the Paperwork Reduction Act of 1980.

Memorandum of Law

The Service published its Memorandum of Law, required by section 4 of Executive Order 12291, in the *Federal Register* dated August 3, 1987 (52 FR 28717).

Authorship

The primary author of this amendment is Greg Esslinger, Office of Migratory Bird Management, working under the direction of Rollin D. Sparrowe, Chief.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Transportation, Wildlife.

For the reasons set out in the preamble, Title 50, Chapter I, Subchapter B, Part 20, Subpart K is amended as follows:

PART 20—[AMENDED]

1. The authority citation for Part 20 continues to read as follows:

Authority: Migratory Bird Treaty Act, sec. 3, Pub. L. 65-186, 40 Stat. 755 (16 U.S.C. 701-708h); sec. 3(h), Pub. L. 95-616, 92 Stat. 3112 (16 U.S.C. 712).

Note.—The annual hunting regulations provided for by § 20.105 of 50 CFR Part 20 will not appear in the Code of Federal Regulations because of their seasonal nature.

2. Section 20.105 on page 36519 of the September 29, 1987, *Federal Register* is amended by revising the table of Mississippi Flyway point values for duck species and sexes to read as follows (the introductory paragraph is being republished):

§ 20.105 Seasons, limits, and shooting hours for waterfowl, coots and gallinules.

Subject to the applicable provisions of the preceding sections of this part, the areas open to hunting, the respective open seasons (dated inclusive), the shooting and hawking hours, and the daily bag and possession limits on the species designated in this section are prescribed as follows:

* * * * *

Point system—Ducks and mergansers. The Mississippi Flyway States selecting the point system bag limits on

designated species are listed in the table above.

The daily bag limit is reached when the point values of the last bird taken added to the sum of the point value of the other birds already taken during that day reaches or exceeds 100 points. The possession limit is the maximum number of birds of species and sex which could have legally been taken in 2 days.

The point values assigned to the species and sexes are as follows:

Mississippi Flyway

100 points: Black duck, Female mallard
70 points: Wood duck, Redhead, Hooded merganser
20 points: Blue-winged teal, Green-winged teal, Cinnamon teal, Wigeon, Shoveler, Gadwall, Scaup, Mergansers (except hooded).
35 points: Male mallard, Pintail, and all other species of ducks.

Note.—All areas of the flyway are closed to canvasback hunting.

* * * * *

Date: November 18, 1987.

Susan Recce,
Acting Assistant Secretary for Fish and Wildlife and Parks.
[FR Doc. 87-27864 Filed 12-3-87; 8:45 am]
BILLING CODE 4310-55-M

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 649**

[Docket No. 70756-7231]

American Lobster Fishery

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Final rule.

SUMMARY: NOAA issues this final rule implementing Amendment 2 to the Fishery Management Plan for the American Lobster Fishery (FMP), which: (1) Increases the minimum legal carapace length for American lobsters; (2) prohibits the possession of V-notched female American lobsters throughout the range of the stock; and (3) enhances enforceability of the FMP's existing prohibition throughout the Nation of the possession of egg-bearing or V-notched female American lobsters, or lobsters under the legal minimum size taken in violation of the Magnuson Fishery Conservation and Management Act. The intended effect is to conserve and manage the American lobster resource to promote full utilization by the U.S. fishing industry.

EFFECTIVE DATE: December 31, 1987.

ADDRESSES: Copies of the amendment, the environmental assessment, and the regulatory impact review/regulatory flexibility analysis are available from Douglas G. Marshall, Executive Director, New England Fishery Management Council, Suntaug Office Park, 5 Broadway, Saugus, MA 01906.

FOR FURTHER INFORMATION CONTACT:

Kathi L. Rodrigues, Resource Management Specialist, 617-281-3600, ext. 324.

SUPPLEMENTARY INFORMATION: The FMP, which was prepared by the New England Fishery Management Council (Council), is implemented by regulations appearing at 50 CFR Part 649. The objective of the FMP is a unified regional management program for American lobsters (*Homarus americanus*), to promote conservation, to reduce the possibility of recruitment failure, and to allow full utilization of the resource by the U.S. fishing industry. Amendment 2 to the FMP was prepared by the Council and a notice of availability (52 FR 27031, July 17, 1987) and a proposed rule (52 FR 28732, August 3, 1987) were published. Public comments were invited until September 10, 1987. Amendment 2: (1) Increases the 3 $\frac{3}{4}$ -inch minimum legal carapace length for American lobsters to 3 $\frac{1}{2}$ inches in four $\frac{1}{32}$ -inch increments, effective January 1, 1988, 1989, 1991, and 1992; (2) prohibits the possession of V-notched female American lobsters throughout the range of the stock; and (3) facilitates enforcement of the Nationwide prohibition against possession of egg-bearing lobsters, V-notched female lobsters, and lobsters that are smaller than the minimum size set forth in the FMP, and taken in violation of the Magnuson Act. There is a rebuttable presumption that any non-conforming lobsters found in interstate commerce were taken in violation of the Magnuson Act. Maine is adopting this identical schedule of increases and Massachusetts and Rhode Island will follow suit.

Several comments were received which indicate that there is confusion over who this rule applies to and how the rebuttable presumption will operate. This issue merits explanation and is discussed below.

Part 649 applies to fishing in waters of the exclusive economic zone (EEZ) and requires that fishermen who wish to fish in the EEZ must apply for and receive Federal permits or federally endorsed State permits for vessels. As an additional conservation measure, this part conditions the permits so that all vessels authorized to fish in the EEZ

must abide by Federal rules wherever they fish. This is typically referred to as the permit election process. Therefore, the size requirements of this part apply to lobsters caught in State waters from vessels permitted to catch lobsters in the EEZ either under a Federal permit or a federally endorsed State permit. This part does not apply to lobsters caught in State waters by fishermen fishing with vessels not permitted to harvest lobster in the EEZ. Lobsters from foreign waters are also not required to conform to the minimum size limits of this part.

Because of the high percentage of lobster fishermen subject to this part through the permit election process, and the relatively small number of lobster fishermen who are not, there is a good basis for presuming that undersized lobsters detected in interstate commerce have been taken in violation of the Magnuson Act, and this final rule establishes a rebuttable presumption to that effect. Consequently, persons lawfully possessing undersized lobsters are afforded an opportunity to rebut the presumption that they were taken in violation of the Act. A document showing that undersized lobsters were harvested from State waters by a vessel which was not permitted to fish in the EEZ will be sufficient to rebut the presumption. For nonconforming lobsters caught in foreign waters, the presumption may be rebutted by a valid bill of lading or shipping document indicating the country of origin.

The size requirements and rebuttable presumption of this rule do not affect prevailing State possession regulations governing minimum lobster size. Rebutting the presumption of this rule does not necessarily make possession of non-conforming lobsters legal at their final destination in the United States. Lobsters may be shipped to any State, but they must be legally harvested under the law of the State or country of origin and they must meet the receiving State's possession size limit for lobsters. Imported lobsters from another State which have been illegally harvested or which violate a receiving State's law prohibiting the possession of undersized lobsters may constitute a Federal violation of the Lacey Act, as well as a violation of the law of the receiving State or the law of the country or State of origin. If the illegal harvest was from the EEZ, or by a vessel permitted to fish in the EEZ, the Magnuson Act and implementing regulations would also be violated.

The preamble to the proposed rule to implement Amendment 2 described these measures and their rationale and is not repeated here.

Comments and Responses

Written comments were submitted by the U.S. Coast Guard, the U.S. Department of the Interior, the New Hampshire Fish and Game Commission (N.H. F&GC), the Fisheries Council of Canada (FC-Canada), the New Jersey Department of Environmental Protection (N.J. DEP), the New York Department of Environmental Conservation (N.Y. DEC), the Entanglement Network Coalition (ENC), and NMFS.

Comment: The Coast Guard commented that the 5-year incremental increases would create an unnecessary expense because of the need to retrain and outfit their personnel with new gauges following every increase. The Coast Guard recommended that the full increase be implemented at one time with a temporary moratorium on enforcement.

Response: The purpose of the incremental increase is to minimize the economic burden caused by the short-term losses associated with a size increase. The Council believes that, based on a similar increase implemented by Rhode Island, the negative impact on landings and revenues are reduced when accomplished over time. A single increase would create a more severe economic disturbance in the industry. In addition, if a single increase were implemented with a temporary moratorium on enforcement, it would delay the expected long-term economic benefits and possibly threaten the resource because, without enforcement, harvesters would probably ignore the conservation measure and land undersized lobsters in order to realize a short-term gain. Therefore, the incremental increases provide the best possibility of realizing the expected benefits of this measure, while minimizing the short-term impacts. In order to reduce expenses, the Coast Guard may wish to consider retooling the gauges they have, rather than purchasing new ones.

Comment: The Coast Guard and NMFS' Office of Enforcement commented that the prohibition on the possession of V-notched lobsters could not be enforced because the preamble to the proposed rule included the Council's recommendation that no civil penalty be imposed if the V-notched lobsters are returned to the natural environment. NMFS' Office of Enforcement also suggested that definitions for V-notched and whole lobsters also be included.

Response: The preamble to the proposed rule states that, while NOAA will consider the Council's recommendation, NOAA has an

obligation to enforce all regulations implementing the FMP. This position has not changed. The suggested definitions have been added.

Comment: The N.J. DEP, noting the likelihood that New Jersey would not follow the 5-year scheduled increases, inquired whether the Nationwide prohibition on possession of eggbearing, V-notched female or sublegal sized lobsters taken in violation of the FMP would affect the sale of legally landed New Jersey lobsters. Also, New Jersey would oppose this amendment if it overrides State size regulations and allows imports smaller than New Jersey's limit to compete with the local product.

Response: Lobster vessels holding only a State lobster permit and harvesting lobsters solely within State waters will be subject to the regulations of that State and not these Federal regulations. However, if a vessel has a Federal lobster permit or a State lobster permit Federally endorsed for the exclusive economic zone (EEZ), then the catch from the vessel will be subject to these regulations. Lobsters shown to have been caught legally in State waters by vessels not having a Federal permit need not meet the Federal minimum size limit and may be shipped to any State, but they must meet the receiving State's size limit. Thus, this rule will not override New Jersey's minimum size regulations. Imported lobsters, or lobsters from another State, which violate a State law prohibiting possession of sublegal sized lobsters, may constitute a violation of the Lacey Act as well as the law of the receiving State.

Comment: The N.Y. DEC commented that the national prohibition would place a presumption of guilt on New York residents in possession of lobsters smaller than the Federal limit, unless they can provide evidence that the lobsters were legally landed from State waters. New York has asked for clarification of the required evidence in the final rule. New York also asked for a clarification of the evidence required to ship lobsters smaller than the Federal size limit to other States having limits smaller than the Federal size limit or no size limits at all.

Response: The National prohibition of this rule applies to lobsters taken from the EEZ and to lobsters taken by a vessel having a Federal lobster permit, or having a State lobster permit Federally endorsed for fishing in the EEZ. Vessels that fish exclusively in State waters and do not have a Federal permit or a Federally endorsed State

permit are not subject to the requirement of this rule.

The documentation required to rebut the presumption that a lobster which does not conform to the requirement of these regulations was taken in violation of the Magnuson Act is:

(1) For imported lobsters—a valid bill of lading or shipping document showing the country of origin;

(2) For lobsters harvested in State waters—a document showing that the lobsters were harvested from State waters by a vessel which does not possess a Federal permit. For example, a copy of the bill of sale for the undersized lobsters, including the name of the harvesting vessel and the number of its State permit which is not endorsed for fishing in the EEZ.

Comment: The N.H. F&GC submitted a Resolution opposing the V-notch provision as well as any increase in minimum size without further study of the economics and biology of the fishery. The Resolution states that the N.H. F&GC does not support the size increase for legal, political, and socioeconomic reasons. Further, the Resolution states that the national prohibition preempts New Hampshire's management prerogatives.

Response: As explained in response to other comments, the national prohibition does not preempt State regulations or a State's management prerogatives within its territorial sea. Vessels permitted by New Hampshire to harvest lobsters solely within State waters will be subject only to New Hampshire's regulations regarding minimum size. Conversely, if the holder of a New Hampshire lobster permit has the permit Federally endorsed or is found harvesting lobsters in the EEZ, the permit holder will be subject to this rule. Although the N.H. F&GC has requested further study before the amendment is approved, the Secretary of Commerce has determined that sufficient analysis of the fishery has been considered and that the amendment is consistent with the national standards set forth in 16 U.S.C. 1851(a) and other applicable law.

Comment: FC-Canada was concerned that the amendment may actually be a trade barrier rather than a conservation measure. FC-Canada recommended that a bill of lading or other transportation document be sufficient evidence to rebut the presumption that these lobsters were taken in U.S. waters.

Response: A valid shipping certificate or bill of lading stating the jurisdiction they came from is sufficient to rebut the presumption that the lobsters were taken in U.S. waters.

Comment: The ENC supported the proposed rule and encouraged

modifying the rule to address the threat to lobster resources posed by non-degradable lost or ghost traps.

Response: The subject of entanglement was not analyzed during the development of Amendment 2 and, therefore, it would be inappropriate to include any entanglement measures in this rule. However, the commenter may wish to bring this matter to the attention of the Council (see "ADDRESSES"), which may propose an additional amendment to the FMP.

Changes From the Proposed Rule

Except that definitions for "V-notched lobster" and "whole lobster" are added, no changes have been made to the regulatory text published in the proposed rule for Amendment 2 (52 FR 28732, August 3, 1987) as a result of public comments, which are addressed above.

Another proposed rule (52 FR 27564, July 22, 1987), unrelated to Amendment 2, pertaining to the expiration date of fishing permits in § 649.4(d) and the numbering system used to identify lobster gear in § 649.21(a)(1) has been available for public comment. No comments have been received. Therefore the provisions of these sections, as proposed, are added to this final rule.

Classification

The Director, Northeast Region, NMFS, has determined that Amendment 2 as approved is necessary for the conservation and management of the American lobster resource and that it is consistent with the Magnuson Act and other applicable law.

The General Counsel of the Department of Commerce certified to the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities.

The Council prepared a regulatory impact review that concluded that this rule would have the following economic effects. The rule is expected to reduce exvessel revenues by \$4.2 million in the first year, assuming that all other factors, such as recruitment, remain constant, and increase revenues after the fifth year. There are an estimated 8,400 commercial lobstermen, both full- and part-time, not including those employed on trawlers which occasionally land lobsters. The average loss per lobsterman is expected to be about \$500 in the first year of implementation. From the tenth year onward, the increase in exvessel revenues will be from \$2.0 million (if there are no positive stock size-recruitment effects) to \$38.6 million (if

positive stock size-recruitment effects are considered). The average expected gain would be about \$4,800 per lobsterman, using the average of the estimates derived from biological models. The rule is expected in its first year to decrease the lobstermen's revenues by 4.8 percent in the Gulf of Maine, by 0.9 percent in the inshore lobster fishery south of Cape Cod, and by 1.6 percent in the offshore fishery.

Extending the prohibition against landing V-notched lobsters will initially decrease the exvessel revenues of about 2,100 commercial lobstermen in Massachusetts and New Hampshire by about \$259,000, or an average of about \$123 per lobsterman. However, it should be noted that V-notched lobsters might have already been voluntarily released by other lobstermen who could have landed them and that this measure is expected to increase the spawning potential of Gulf of Maine lobsters by 47 percent. In public hearings held in Portsmouth, New Hampshire, and Peabody, Plymouth, and Provincetown, Massachusetts, there was nearly unanimous support by lobstermen for extending the protection of V-notched lobsters throughout their range. This measure is not expected to have any impacts on lobstermen in the Georges Bank fishery or south of Cape Cod.

Administrative, enforcement, and paperwork and recordkeeping requirements are expected to remain unchanged; thus, there are no impacts on Federal, State, or local government agencies. A lobsterman's operating expenses are not expected to be affected. Rather than a decrease in employment, it is expected that inshore lobstermen will initially experience a general decrease in revenues without any substantial change in employment, and then an increase after five years. Offshore lobstermen are not expected to experience any decrease in revenues; however, there are insufficient data on employment per vessel and a lack of models to determine the employment response to revenue changes in this sector.

The purpose of Amendment 2 is to enhance productivity. It is expected to increase annual lobster landings from 2.3 to 35.2 percent after five years, increase the size of the average "chicken" lobster by 12 percent, and increase egg production by 92 percent due to the larger carapace size and the V-notch program. You may obtain a copy of the amendment from the Council at the address above.

The Council prepared an environmental assessment for this amendment and the Assistant

Administrator for Fisheries, NOAA, found that there will be no significant impact on the environment as a result of this rule. Thus, it does not alter the final environmental impact statement of the FMP.

While this rule does not contain a collection of information requirement for the purposes of the Paperwork Reduction Act, it refers to an existing requirement which has been cleared by the Office of Management and Budget under OMB Control Number 0648-0097.

The Council determined that this rule will be implemented in a manner that is consistent, to the maximum extent practicable, with the approved coastal zone management programs of Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, Delaware, Maryland, and New Jersey. This determination has been submitted for review by the responsible State agencies under section 307 of the Coastal Zone Management Act.

List of Subjects in 50 CFR Part 649

Fisheries, Reporting and -
recordkeeping requirements.

Dated: December 1, 1987.

Bill Powell,

Executive Director, National Marine
Fisheries Service.

For the reasons set out in the preamble, 50 CFR Part 649 is amended as follows:

PART 649—AMERICAN LOBSTER FISHERY

1. The authority citation for 50 CFR Part 649 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 649.2, the definitions of *Fishery conservation zone (FCZ)* and *V-notch conservation area* are removed and new definitions for *Exclusive economic zone (EEZ)*, *V-notched lobster* and *Whole lobster* are added in alphabetical order to read as follows:

§ 649.2 Definitions.

Exclusive economic zone (EEZ) means the zone established by Presidential Proclamation 5030, dated March 10, 1983, and is that area adjacent to the United States which, except where modified to accommodate international boundaries, encompasses all waters from the seaward boundary of each of the coastal States to a line on which each point is 200 nautical miles from the baseline from which the

territorial sea of the United States is measured.

V-notched lobster means any lobster bearing a V-shaped notch in the right flipper next to the middle flipper or any female lobster which is mutilated in a manner which could hide or obliterate such a mark. The right flipper will be examined when the underside of the lobster is down and its tail is toward the person making the determination.

Whole lobster means a lobster with an intact and measurable body (tail and carapace). A whole lobster may have one or both claws missing.

3. In § 649.4, paragraph (d) is revised to read as follows:

§ 649.4 Vessel permits.

(d) *Expiration.* A permit expires on December 31, or when the owner or name of the vessel changes.

4. In § 649.7, paragraph (a)(5) is revised and a new paragraph (c) is added to read as follows:

§ 649.7 Prohibitions.

(a) * * *

(5) To possess any V-notched female American lobsters throughout the range of the stock;

(c) The possession of egg-bearing female American lobsters, V-notched female American lobsters, or American lobsters that are smaller than the minimum size set forth in § 649.20(b) of this part, will be *prima facie* evidence that such lobsters were taken or imported in violation of these regulations. Evidence that such lobsters were harvested by a vessel not holding a permit under this part and fishing exclusively within State or foreign waters will be sufficient to rebut the presumption.

5. In § 649.20, paragraphs (b) and (c) are revised and paragraph (f) is removed, to read as follows:

§ 649.20 Harvesting and landing requirements.

(b) *Carapace length.* All American lobsters landed on the dates set forth must have a minimum carapace length as follows:

Effective Dates and Minimum Carapace Length

January 1, 1985, through December 31, 1987: 3 $\frac{3}{16}$ inches

January 1, 1988, through December 31, 1988: 3 $\frac{1}{2}$ inches

January 1, 1989, through December 31, 1990:¹ 3 $\frac{3}{4}$ inches
January 1, 1991, through December 31, 1991: 3 $\frac{3}{8}$ inches
January 1, 1992, and beyond: 3 $\frac{5}{16}$ inches

¹ By January 1, 1990, escape vents in traps must be compatible with a minimum carapace length of 3 $\frac{3}{16}$ inches.

(c) *Mutilation.* It is unlawful for any person to remove meat or any body appendages from any lobster before landing, or to have in possession on board any lobster part other than whole lobsters.

6. In § 649.21, paragraph (a)(1) is revised; paragraphs (c) (1), (2), and (3) are redesignated (c)(1) (i), (ii), and (iii); paragraph (c) introductory text is designated (c)(1), an initial phrase is added, and the word "All" is set in lower case; a new paragraph (c)(2) is added; the text of paragraph (d) is designated (d)(1); and a new paragraph (d)(2) is added, to read as follows:

§ 649.21 Gear identification, marking, and escape vent requirements.

(a) * * *

(1) A number assigned by the Regional Director; and/or

(c) *Escape vents.* (1) Until January 1, 1990, all * * *

(2) On January 1, 1990, rectangular or circular escape vents compatible with a minimum carapace length of 3 $\frac{3}{16}$ inches will be required.

(d) * * *

(2) Following the effective date of each carapace length increase set forth in § 649.20(b) of this part, any dealer/wholesaler will have 180 days in which to dispose of any lobsters purchased or received in the prior year which do not meet the new minimum carapace length increase.

§§ 649.4, 649.7, 649.20, 649.21, and 649.22 [Amended]

7. In addition to the amendments set forth above, the initials "FCZ" are removed and the initials "EEZ" are added in their place in the following places:

§ 649.4(a) (1), (2), and (3);
§ 649.7(a) introductory text and (b)(2);
§ 649.20(a);
§ 649.21(a) introductory text, (b) introductory text and (b)(4) (i), (ii), (iii), and (iv), and (c)(1); and
§ 649.22(b)(1).

[FR Doc. 87-27871 Filed 12-1-87; 3:31 pm]

BILLING CODE 3510-22-M

Proposed Rules

Federal Register

Vol. 52, No. 233

Friday, December 4, 1987

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 109

[INS Number: 1026-87]

Employment Authorization; Classes of Aliens Eligible

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Petition for rulemaking; denial.

SUMMARY: On October 28, 1986 (51 FR 39385) the Immigration and Naturalization Service ("the Service") published a petition for rulemaking submitted by the Federation for American Immigration Reform ("FAIR"). The petition sought the rescission of 8 CFR 109.1(b) relating to employment authorization for aliens in the United States because the petitioner believed that the Service had exceeded its authority in promulgating the regulation. In publishing the FAIR petition, the Service explained that it was taking no position on the issues raised in the petition, but was seeking comments from interested parties. The period for submission of comments was initially designated as from October 28, 1986 to December 29, 1986, but was extended on December 18, 1986 until January 28, 1987 to afford the public an opportunity to submit comments in light of the Immigration Reform and Control Act of 1986. Upon a thorough review of the comments received, the Service now denies the petition.

DATES: The petition is denied as of December 4, 1987.

FOR FURTHER INFORMATION CONTACT: Michael L. Shaul, Senior Immigration Examiner, Immigration and Naturalization Service, 425 I Street, NW., Washington, DC 20536, Telephone: (202) 633-3946.

SUPPLEMENTARY INFORMATION: In publishing the FAIR petition to rescind 8 CFR 109.1(b) the Service sought

comments from interested parties concerning the issues raised in the petition. The Service took no position on the merits of the petition at the time of publication, preferring to carefully evaluate the petition in light of comments from the public.

Subsequent to the publication of the petition, the Immigration Reform and Control Act of 1986 (IRCA) became law. Section 101 of IRCA amended the Immigration and Nationality Act by adding section 274(a) relating to the unlawful employment of aliens. Accordingly, on May 1, 1987 (52 FR 16190) the Service published regulations relating to IRCA which (among other things) transferred 8 CFR Part 109 to 8 CFR Part 274a and significantly expanded the material covered. Although 8 CFR Part 109 has now been removed, this denial of rulemaking will continue to refer to the regulation discussed in the petition as 8 CFR Part 109 for the sake of clarity.

The Service received a total of 99 responses during the period designated for submission of comments, and one response from the Department of the Treasury subsequent to the closing date. Of the 99 comments, 46 were in favor of the petition and 53 were opposed. Comments were received from a wide spectrum of interested parties, ranging from local to national to international governmental entities, and from private individuals to business and educational institutions to public interest groups. Likewise, the extent of the comments ranged from simple statements of support or opposition to fairly thorough legal and historical discussions. Some writers chose to comment only on the one or two aspects of the petition with which they were most familiar, while others chose to comment on all aspects. Regardless of the source, the extent or the scope, all comments were carefully reviewed and the arguments presented taken into account. Finally, the Service would like to express its appreciation to all who took the time to submit comments.

The FAIR petition presented three premises for rescinding the regulation. The remainder of this discussion will deal with each of these premises in light of the comments received from persons on both sides of the issues:

Premise A: The Regulation is Inconsistent With the Purpose of the Immigration and Nationality Act ("the Act")

The petitioner contends that the purpose of the Act is the protection of the American labor force, and that because the regulation is inconsistent with this purpose, it should be rescinded. Opponents of the petition counter that FAIR has over-simplified the purpose of the Act. In fact, the Act is a very complex statute which has many different purposes, some of which may appear at time to be in conflict with others. Among the goals of the Act not mentioned by FAIR are: Supporting international exchange, encouraging family reunion, protecting those who fear persecution, facilitating diplomatic relations, fulfilling international treaty requirements, providing due process for deportable aliens, and (in certain instances) providing some measure of humanitarian assistance to meritorious cases. Since each of the categories of aliens authorized to accept employment by 8 CFR 109.1(b) relates to at least one of these goals, the regulation is not inconsistent with the purposes of the Act.

Additionally, FAIR states that the labor certification requirements of section 212(a)(14) of the Act are being circumvented because the Service does not keep statistical records of the number of aliens permitted to work under the provisions of 8 CFR 109.1(b). Although the Service has not kept such records in the past, it has never been unconcerned with the impact of the regulation on the American labor market. While recognizing the other goals of the Act, the Service has taken reasonable measures to protect the labor market. The employment authorized by 8 CFR 109.1(b) is normally of very limited duration and only under conditions set forth in that Part or in other Parts referred to in the regulation. These conditions, combined with the fact that most of the classes enumerated in 8 CFR 109.1(b) are very small to begin with, mean that the total number of aliens authorized to accept employment is quite small and the impact on the labor market is minimal. The regulatory conditions include:

1. The dependent of a foreign government official or international organization employee is not allowed to

accept employment in a "Schedule B" occupation. This schedule, prepared by the Department of Labor, lists those occupations for which a labor certificate may not be granted.

2. A nonimmigrant student may accept on-campus employment only if it does not displace a United States resident, may accept employment for practical training only in areas where such training is not available in his or her homeland, and may accept employment due to economic necessity only after completion of the first year of studies and after establishing that the need was unforeseeable.

3. The spouse of an exchange visitor may not be authorized employment for the support of the principal alien.

4. An asylum applicant who has filed a frivolous application may not be granted employment authorization.

5. An adjustment applicant must first be the beneficiary of an immigrant visa petition (unless the applicant qualifies as a "special immigrant") and an immigrant visa number (if required) must be immediately available.

6. An applicant for suspension of deportation must establish that he or she has an economic need to work.

7. A deportable alien under voluntary departure must establish that he or she merits favorable exercise of the district director's discretion. The regulation sets forth four conditions to be considered by the district director in reaching his decision.

8. An alien who has been placed in deferred action status must establish an economic need to work.

Furthermore, it should be noted that although the number of aliens authorized to work under 8 CFR Part 109 (now 8 CFR Part 274A) is relatively small and was previously considered to be not worth recording statistically, the Service is exploring ways of formalizing procedures for requesting employment authorization which will result in the generation of statistical reports.

Premise B: The Regulation as Promulgated by the INS is an Ultra Vires Act

This second premise is directly related to the first. FAIR contends that the Attorney General had no statutory authority to promulgate regulations and rejects the Service's stated position that the relevant authority was conferred upon the Attorney General by section 103(a) of the Act as passed by Congress. That section states, in pertinent part:

The Attorney General shall be charged with the administration and enforcement of this Act and all other laws relating to the

immigration and naturalization of aliens, except, insofar as this Act or such laws relate to the powers, functions, and duties conferred upon the President, the Secretary of State, the officers of the Department of State, or diplomatic or consular officers: *Provided, however,* That determination and ruling by the Attorney General with respect to all questions of law shall be controlling. * * * He shall establish such regulations * * * as he deems necessary for carrying out his authority under the provisions of this Act.

The authority of the Attorney General is not limited to the enforcement of one section of the Act dealing with labor certifications; it extends to the administration and enforcement of the Act as a whole. In determining what regulations are necessary for carrying out his authority, the Attorney General cannot operate in a vacuum, but must view the Act as it relates to multiple national and international policy issues. As Emanuel Celler, Chairman of the House Committee on the Judiciary, stated when the 1952 Act was under consideration: "the law * * * affects basically foreign policy, constitutional guarantees, public welfare, the health, the economy, and the productivity of the Nation." (Congressional and Administrative News, 82nd Congress, Second Session, 1952, v.2, p. 1750). It requires a simplistic view of the purposes of the Act and a narrow view of the mission of the Service to contend that regulations should be promulgated solely for the purpose of preventing any aliens without labor certification from being authorized to accept employment. Assuming for the sake of argument that section 103(a) of the Act did not vest in the Attorney General the necessary authority to promulgate 8 CFR 109.1(b), such authority is apparent in the new section 274A.(h)(3) of the Act which was created by the Immigration Reform and Control Act of 1986. Section 274A.(h)(3) reads:

Definition of Unauthorized Alien.—As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or the Attorney General.

Despite the fact that on December 18, 1986 (51 FR 45338) the Service published this definition and extended the time for submission of comments until January 28, 1987, very few of the petition's proponents even mentioned the new Act. One notable exception was the petitioner itself, which submitted a supplemental statement supporting the petition. The petitioner claimed that the phrase "authorized to be so employed

by this Act or the Attorney General" does not recognize the Attorney General's authority to grant work authorization except to those aliens who have already been granted specific authorization by the Act. On the contrary, the only logical way to interpret this phrase is that Congress, being fully aware of the Attorney General's authority to promulgate regulations, and approving of the manner in which he has exercised that authority in this matter, defined "unauthorized alien" in such fashion as to exclude aliens who have been authorized employment by the Attorney General through the regulatory process, in addition to those who are authorized employment by statute.

Premise C: The Regulation Undermines the Labor Certification Provision

While there can be no doubt that the classes of aliens enumerated in the regulation are authorized to work without first having to obtain a labor certification, the contention that the labor certification provision is undermined is without foundation. In creating the labor certification process, Congress intended that it apply only to certain classes of aliens: third, sixth and nonpreference immigrants and H-2 nonimmigrants. Creation of the process in no way implies that Congress intended to restrict the authority of the Attorney General to promulgate regulations necessary for the administration of the Act, including regulations which authorize certain aliens to accept employment under appropriate circumstances. By limiting the circumstances under which aliens may be granted employment authorization (as discussed above), the Attorney General has assured that the regulations do not circumvent the intent of the labor certification provisions of the statute.

Upon consideration of all of the representations made by the petitioner, the comments submitted by interested parties, the legislative history of the Act and other relevant factors, it has been determined that the petition for rulemaking is without merit. Accordingly, the petition is hereby denied.

Dated: November 30, 1987.

Richard E. Norton,

Associate Commissioner, Examinations, Immigration and Naturalization Service.

[FR Doc. 87-27905 Filed 12-3-87; 8:45 am]

BILLING CODE 4410-10-M

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39****[Docket No. 87-NM-154-AD]**

Airworthiness Directives; the de Havilland Aircraft Company of Canada, a Division of Boeing of Canada, Ltd., Model DHC-7 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes a new airworthiness directive (AD), applicable to certain de Havilland Model DHC-7 series airplanes, which would require replacement of aluminum alloy heat shield washers with stainless steel washers. This proposal is prompted by reports of cracking found in the aluminum washers. This condition, if not corrected, could lead to in-flight separation of the heat shield from the wing, and consequent injury to people on the ground.

DATE: Comments must be received no later than January 27, 1988.

ADDRESSES: Send comments on the proposal in duplicate to Federal Aviation Administration, Northwest Mountain Region, Office of the Regional Counsel (Attn: ANM-103), Attention: Airworthiness Rules Docket No. 87-NM-154-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168. The applicable service information may be obtained from The de Havilland Aircraft Company of Canada, a Division of Boeing of Canada, Ltd., Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the FAA, New England Region, New York Aircraft Certification Office, 181 South Franklin Avenue, Room 202, Valley Stream, New York.

FOR FURTHER INFORMATION CONTACT: Mr. Vito Pulera, Systems and Equipment Branch, ANE-173, New York Aircraft Certification Office, FAA, New England Region, 181 South Franklin Avenue, Room 202, Valley Stream, New York 11581; telephone (516) 791-6427.

SUPPLEMENTARY INFORMATION:**Comments Invited**

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications

should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this Notice may be changed in light of the comments received. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA/public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the FAA, Northwest Mountain Region, Office of the Regional Counsel (Attn: ANM-103), Attention: Airworthiness Rules Docket No. 87-NM-154-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

Discussion

There have been numerous reports of cracking of the aluminum alloy washers used for the installation of the upper wing skin heat shield on de Havilland DHC-7 series airplanes equipped with Modification 7/2414. Cracking has been determined to be due to the high temperatures experienced in this area of the airplane. This condition, if not corrected, could result in separation of the heat shield from the airplane during flight, and consequent injury to people on the ground.

De Havilland has issued Service Bulletin No. 7-57-29, dated August 1, 1986, which describes replacement of the aluminum alloy washers with stainless steel washers. Transport Canada, which is the airworthiness authority of Canada, issued Airworthiness Directive CF-87-11 on September 22, 1987, making compliance with the service bulletin mandatory.

This airplane is manufactured in Canada and type certificated in the United States under the provisions of § 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement.

Since this condition is likely to exist or develop on other airplanes of this same type design, an AD is proposed which would require replacement of the aluminum washers in accordance with the service bulletin previously mentioned.

It is estimated that 44 airplanes of U.S. registry would be affected by this AD,

that it would take approximately 8 manhours per airplane to accomplish the required actions, and that the average labor cost would be \$40 per manhour. The required parts would be provided by the manufacturer at no cost to operators. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be \$14,080.

For these reasons, the FAA has determined that this document (1) involves a proposed regulation which is not major under Executive Order 12291 and (2) is not a significant rule pursuant to the Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and it is further certified under the criteria of the Regulatory Flexibility Act that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities because of the minimal cost of compliance per airplane (\$320). A copy of a draft regulatory evaluation prepared for this action is contained in the regulatory docket.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) as follows:

PART 39—[AMENDED]

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By adding the following new airworthiness directive:

De Havilland Aircraft Company of Canada, a Division of Boeing of Canada, Ltd.:
Applies to Model DHC-7 series airplanes, equipped with Modification No. 7/2414, certificated in any category. Compliance required as indicated, unless previously accomplished.

To preclude the possibility of heat shield separation resulting from the failure of aluminum alloy washers, accomplish the following:

A. Within 60 days or 500 flight hours, whichever occurs first after the effective date of this AD, replace aluminum alloy washers with stainless steel washers, in accordance with the Accomplishment Instructions of de Havilland DHC-7 Service Bulletin No. 7-57-29, dated August 1, 1986.

B. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety and

which has the concurrence of an FAA Principal Maintenance Inspector, may be used when approved by the Manager, New York Aircraft Certification Office, FAA, New England Region.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to The de Havilland Aircraft Company of Canada, A Division of Boeing of Canada, Ltd., Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. These documents may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or FAA, New England Region, New York Aircraft Certification Office, 181 South Franklin Avenue, Room 202, Valley Stream, New York.

Issued in Seattle, Washington, on November 27, 1987.

Frederick M. Isaac,

Acting Director, Northwest Mountain Region.

[FR Doc. 87-27842 Filed 12-3-87; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 352

[Docket No. 78N-0038]

Discussion of Appropriate Testing Procedures for Over-the-Counter Sunscreen Drug Products; Public Meeting and Reopening of the Administrative Record; Extension of Time for Submission of Relevant Data and Notice of Participation

AGENCY: Food and Drug Administration.
ACTION: Public meeting and reopening of the administrative record; extension of time for submission of data and notice of participation.

SUMMARY: The Food and Drug Administration (FDA) is extending to December 18, 1987, the period for submission of relevant data and notice of participation for the public meeting to be held on January 26, 1988, to discuss appropriate testing procedures for over-the-counter (OTC) sunscreen drug products. This action responds to a request to extend the period for submission of relevant data and notice of participation.

DATE: Relevant data and notice of participation by December 18, 1987.

ADDRESS: Relevant data, notice of participation, and comments to the Dockets Management Branch, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Saul Bader or Jeanne Rippere, Center for Drug Evaluation and Research (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8003.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 4, 1987 (52 FR 33598), FDA issued a notice of a public meeting and reopening of the administrative record for a discussion of appropriate testing procedures for OTC sunscreen drug products. Interested persons were given until December 3, 1987, to submit relevant data and notice of participation for a meeting. The meeting is to be held on January 26, 1988, at 9 a.m., in Conference Rooms D and E, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

A cosmetics manufacturers' association has informed the agency that it plans to file extensive comments in response to the notice published in the *Federal Register* of September 4, 1987. However, because of the complexity of the various issues, the need to reconcile the views of large numbers of interested parties (over 20 companies), and the intervention of the Thanksgiving holiday, the association has stated that it will not be able to meet the December 3, 1987, deadline for filing relevant data and notice of participation. Therefore, the association has requested that the time period for submission of data and notice of participation be extended to December 18, 1987.

FDA has carefully considered the request and believes that the data provided by, and the participation of, the association may be of assistance in establishing the appropriate testing procedures for OTC sunscreen drug products. Therefore, an extension of the time period for submission of relevant data and notice of participation is in the public interest. Accordingly, the period for submission of relevant data and notice of participation is extended to December 18, 1987. Relevant data and notices of participation may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday. The date of this meeting and other dates provided in the September 4, 1987, notice remain unchanged.

Dated: December 1, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-27929 Filed 12-2-87; 10:49 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation Enforcement

30 CFR Part 952

Closing of Public Comment Period; Abandoned Mine Land Reclamation Program

AGENCY: Office of Surface Mining Reclamation Enforcement, Interior.

ACTION: Closing public comment period; Abandoned Mine Land Reclamation Plan.

SUMMARY: On June 10, 1982, the Hopi Tribe submitted to OSMRE its proposed Abandoned Mine Land Reclamation Plan (Plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA) (30 CFR Chapter 7 subchapter R) as published in the *Federal Register* (FR) on June 30, 1982, 47 FR 28574-28604. OSMRE requested public comment on the adequacy of the Tribe's Plan, 47 FR 31709-31711 (July 22, 1982) and has left the comment period open pending authorizing legislation. On July 11, 1987, legislation was enacted authorizing the Crow, Hopi, and Navajo Tribes to obtain abandoned mine land reclamation programs without first having to obtain approval of Tribal surface mining regulatory program. OSMRE is giving notice of its intent to close the period for comment on the Hopi Tribes's Abandoned Mine Land Reclamation Plan.

DATES: *Written Comments:* OSMRE will accept written comments on the proposed rule until 4:00 p.m. Mountain time January 4, 1988. Comments received after that date will not necessarily be considered in the decision process.

Public Hearing: A public hearing on the proposed Hopi Abandoned Mine Land Reclamation (AMLR) Plan has been scheduled for 9:30 a.m. local time, on December 24, 1987 in the conference room of the Albuquerque Field Office, Office of Surface Mining Reclamation and Enforcement, 625 Silver Avenue, SW, Albuquerque, New Mexico 87102. Any person interested in making an oral or written presentation at the hearing should contact Robert Hagen, Field Office Director at the OSMRE

Albuquerque Field Office by 4:00 p.m. local time on December 21, 1987. If only three or fewer persons have so contacted Mr. Hagen, a meeting rather than a hearing may be held. A summary report of the meeting will be included in the Administrative Record.

ADDRESSES: Written comments and requests for a hearing should be mailed to: Robert Hagen, Director, Albuquerque Field Office, Office of Surface Mining Reclamation and Enforcement, 625 Silver Avenue, SW., Albuquerque, New Mexico 87102. Copies of the Navajo Plan and the Administrative Record of the Hopi Plan are available for public review and copying at the OSMRE and the Hopi offices listed below, Monday through Friday, from 9:00 a.m. to 4:00 p.m. excluding holidays. Each requestor may receive, free of charge, one copy of the proposed plan by contacting OSMRE's Albuquerque Field Office.

Hopi AML Agency: Hopi Tribal Council, Office of Natural Resources, P.O. Box 123, Kykotsmovi, Arizona 86039.

OSMRE's Field Office processing the Plan: Office of Surface Mining Reclamation and Enforcement, Albuquerque Field Office, 625 Silver Avenue, SW., Albuquerque, New Mexico 87102.

Office of Surface Mining Reclamation and Enforcement, Administrative Records Office, 1100 "L" Street, NW., Room 5131, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Wayne D. Oliver, Supervisory AML Program Specialist at the Albuquerque Field Office (505) 766-1486.

SUPPLEMENTARY INFORMATION:

I. Background

II. Discussion of Proposed Abandoned Mine Land Reclamation Plan

I. Background

In 1982, the Hopi Tribe submitted to OSMRE its proposed Abandoned Mine Reclamation Plan under the Surface Mining Control and Reclamation Act of 1977 (SMCRA), Pub. L. 95-87. At that time OSMRE requested public comments on the adequacy of the proposed Plan, 47 FR 31709-31711 (July 22, 1982). Following an internal review of the proposed Plan and public comments, OSMRE met with the Hopi Tribe to discuss certain revisions to its Plan. In 1983, the Hopi Tribe submitted a revised reclamation plan. Since OSMRE lacked authority under SMCRA to proceed further in the process for approving Tribal reclamation plans, OSMRE took no further action on the Hopi Tribe's proposed Plan. The public comment period, however, remained open pending authorizing legislation.

On July 11, 1987, the President signed the fiscal year 1987 supplemental appropriations bill which included authority for the Crow, Hopi, and Navajo tribes to obtain abandoned mine land reclamation programs without first having to obtain approval of Tribal surface mining regulatory programs. In response to this legislation, OSMRE notified the Hopi Tribe that it was now able to consider final action on the proposed Plan. This notice announces that OSMRE is in the process of finalizing its review of the Hopi AMLR Plan and that the public comment period will close on January 4, 1988.

Title IV of the Surface Mining Control and Reclamation Act of 1977 (SMCRA), Pub. L. 95-87, 30 U.S.C. 1201 *et seq.*, establishes an abandoned mine land program for the purposes of reclaiming and restoring land and water resources adversely affected by past mining. This program is funded by a reclamation fee imposed upon the production of coal. Lands and water eligible for reclamation are those that were mined or affected by mining and abandoned or left in an inadequate reclamation status prior to August 3, 1977, and for which there is no continuing reclamation responsibility under State/Tribal or Federal Law.

Title IV provides that if the Secretary determines that a State or Tribe has developed and submitted a program for reclamation of abandoned mines and has the ability and necessary State or Tribal legislation to implement the provisions of Title IV, the Secretary may approve the State or Tribal program and grant to the State or Tribe exclusive responsibility and authority to implement the provisions of the approved program.

OSMRE has received a proposed AMLR plan from the Hopi Tribe. The purpose of this submission is to determine both the intent and capability to assume responsibility for administering and conducting the provisions of SMCRA and OSMRE's Abandoned Mine Land Reclamation (AMLR) Program (30 CFR Chapter 7, Subchapter R) as published in the *Federal Register* (FR) on June 30, 1982, 47 FR 28574-28604.

This notice describes the nature of the proposed program and sets forth information concerning public participation in the Secretary's determination of whether or not the submitted plan may be approved. The public participation requirements for the consideration of a State or Tribal AMLR Plan are found in 30 CFR 884.13 and 884.14. Additional information may be found under corresponding sections of the preamble to OSMRE's AMLR

Program Rules as published in October 25, 1978 (43 FR 49932-49952).

The receipt of the Hopi Tribe's Plan is the first step in the process that will result in the establishment of a comprehensive program for the reclamation of abandoned mine lands on the Hopi Tribal Lands.

By submitting a proposed Plan, the Hopi Tribe has indicated that it wishes to be primarily responsible for this program. If the submission, as hereafter modified, is approved by the Secretary, the Hopi Tribe will have primary responsibility for the reclamation of abandoned mine lands on Hopi Tribal Lands.

The Department intends to continue to discuss the Hopi Tribe's proposed Plan with representatives of the Tribe throughout the review process. All contacts between OSMRE personnel and representatives of the Tribes will be conducted in accordance with OSMRE's guidelines on contacts with States published September 19, 1979 at 44 FR 54444.

II. Discussion of Proposed Plan

The Hopi Plan is designed to apply the provisions of Title IV of the Surface Mining Control and Reclamation Act (SMCRA) of 1977 to reclamation of abandoned mines on the Hopi Tribal Lands. The Plan includes discussions of criteria for selecting and ranking proposed projects; standards for acquiring, managing, and disposing of land under the AMLR program; public participation policy; and descriptions of proposed projects. The existing environment on the Tribal lands is also described in the Plan.

The following constitutes a summary of the contents of the Hopi Tribe's Reclamation Plan submission:

(a) Designation of authorized Tribal Agency to administer the program.

(b) Tribes's General Counsel's opinion that the designated Agency has the legal authority to operate the program in accordance with the requirements of Title IV of SMCRA, 30 CFR Chapter 7, Subchapter R, and the Tribal Reclamation Plan.

(c) Description of the policies and procedures to be followed in conducting the program including:

- (1) Goals and objectives;
- (2) Project ranking and selection procedures;
- (3) Coordination with other reclamation programs;
- (4) Land acquisition, management, and disposal;
- (5) Reclamation on private land;
- (6) Rights of entry; and
- (7) Public participation in the program.

(d) Description of the administrative and management structure to be used in the program including:

(1) Description of the organization of the designated agency and its relationship to other organizations that will participate in the program;

(2) Personnel staffing policies;

(3) Purchasing and procurement systems and policies; and

(4) Description of the accounting system including specific procedures for operation of the reclamation fund.

(e) Description of the reclamation activities to be conducted under the Tribal Reclamation Plan discussing the known or suspected eligible lands and waters within the Tribal lands and including:

(1) A map showing the general location of known or suspected eligible lands and waters;

(2) A description of the problems occurring on these lands;

(3) How the Plan proposes to address each of the problems.

(f) Description of the conditions prevailing on the different geographic areas of the Tribal lands where reclamation is planned, including:

(1) The economic base;

(2) Significant esthetic, historic or cultural, and recreational values; and

(3) Endangered and threatened plants, fish, and wildlife and their habitat.

The Hopi Tribe has also requested authority to assume responsibility for emergency reclamation activities. Guidelines for assumption of this responsibility are published in the *Federal Register*, 47 FR 42729 (September 29, 1982).

The Hopi Tribal Reclamation Plan for Abandoned Mine Lands can be approved if:

1. The Secretary finds that the public has been given adequate notice and opportunity to comment, and the record does not reflect major unresolved controversies.

2. Views of other Federal agencies have been solicited and considered.

3. The Tribe has the legal authority, policies and administrative structure to carry out the Plan.

4. The Plan meets all the requirements of the OSMRE AMLR Program provisions.

5. It is determined that the Plan is in compliance with all applicable Tribal and Federal laws and regulations.

Date: November 4, 1987.

Brent T. Wahlquist,

Assistant Director, Program Policy, Office of Surface Mining Reclamation and Enforcement.

[FR Doc. 87-27396 Filed 12-3-87; 8:45 am]-

BILLING CODE 4310-05-M

30 CFR Part 953

Reopening and Extension of Public Comment Period; Abandoned Mine Land Reclamation Program

AGENCY: Office of Surface Mining Reclamation and Enforcement Interior.

ACTION: Notice of reopening and extension of public comment period.

SUMMARY: In 1982, the Navajo Tribe submitted to OSMRE its proposed Abandoned Mine Land Reclamation Plan (Plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA), 30 CFR Chapter 7, Subchapter R) as published in the *Federal Register* (FR) on June 30, 1982, 47 FR 28574-28604. OSMRE published notice of the receipt of the Navajo AMLR plan and requested comments, 48 FR 49870-49872 (October 28, 1983). The public comment period closed on November 28, 1983, and no final action was taken by OSMRE due to the lack of authorizing legislation under SMCRA. On July 11, 1987, legislation was enacted authorizing the Crow, Hopi, and Navajo Tribes to obtain abandoned mine land reclamation programs without first having to obtain approval of Tribal surface mining regulatory programs. OSMRE is hereby reopening the public comment period for consideration of the adequacy of the Navajo Tribe's Abandoned Mine Land Reclamation Plan.

DATES: Written Comments: OSMRE will accept written comments on the proposed rule until 4:00 p.m. Mountain Time, January 4, 1988. Comments received after that date will not necessarily be considered in the decision process.

Public Hearing: A public hearing on the proposed Navajo Abandoned Mine Land Reclamation (AMLR) Plan has been scheduled for 9:30 a.m. local time on December 24, 1987 in the conference room of the Albuquerque Field Office, Office of Surface Mining Reclamation and Enforcement, 625 Silver Avenue SW., Albuquerque, New Mexico 87102. Any person interested in making an oral or written presentation at the hearing should contact Robert Hagen, Field Office Director at the OSMRE Albuquerque Field Office by 4:00 p.m. local time on December 21, 1987. If only three or fewer persons have so contacted Mr. Hagen, a meeting rather than a hearing may be held. A summary report of the meeting will be included in the Administrative Record.

ADDRESSES: Written comments and requests for a hearing should be mailed to: Robert Hagen, Director, Albuquerque Field Office, Office of Surface Mining

Reclamation and Enforcement, 625 Silver Avenue SW., Albuquerque, New Mexico 87102. Copies of the Navajo Plan and the administrative record of the Navajo Plan are available for public review and copying at the OSMRE Offices and the Navajo Office listed below, Monday through Friday, from 9:00 a.m. to 4:00 p.m. excluding holidays. Each requestor may receive, free of charge, one copy of the proposed plan by contacting OSMRE's Albuquerque Field Office.

Navajo AML Agency: The Navajo Tribe, Navajo Coal Mining Commission, P.O. Box 1069, Ft. Defiance, Arizona 86039
OSMRE's Field Office processing the Plan: Office of Surface Mining Reclamation and Enforcement, Albuquerque Field Office, 625 Silver Avenue SW., Albuquerque, New Mexico 87102

Office of Surface Mining Reclamation and Enforcement, Administrative Records Office, 1100 "L" Street NW., Room 5131, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Wayne D. Oliver, Supervisory AML Program Specialist at the Albuquerque Field Office, (505) 766-1486.

SUPPLEMENTARY INFORMATION:

I. Background

II. Discussion of Proposed Abandoned Mine Land Reclamation Plan

I. Background

In 1982 the Navajo Tribe submitted to OSMRE its proposed Abandoned Mine Reclamation Plan under the Surface Mining Control and Reclamation Act of 1977 (SMCRA), Pub. L. 95-87. At that time, OSMRE requested public comments on the adequacy of the proposed Plan, 48 FR 49870-49872 (October 28, 1983). Following an internal review of the proposed Plan and public comments, OSMRE met with the Navajo Tribe to discuss certain revisions to its Plan. In 1983 the Navajo Tribe submitted a revised reclamation plan. Since OSMRE lacked authority under SMCRA to proceed further in the process for approving Tribal reclamation plans, the comment period closed November 28, 1983 and OSMRE took no further action on the Navajo Tribe's proposed Plan.

On July 11, 1987, the President signed the fiscal year 1987 supplemental appropriations bill which included authority for the Crow, Hopi, and Navajo tribes to obtain abandoned mine land reclamation programs without first having to obtain approval of Tribal surface mining regulatory programs. In response to this legislation, OSMRE notified the Navajo Tribe that it was reopening its review of their proposed Plan. This notice is seeking public

comment on the adequacy of the proposed Navajo Tribal AMLR Plan.

Title IV of the Surface Mining Control and Reclamation Act of 1977 (SMCRA), Pub. L. 95-87, 30 U.S.C. 1201 *et seq.*, establishes an abandoned mine land program for the purposes of reclaiming and restoring land and water resources adversely affected by past mining. This program is funded by a reclamation fee imposed upon the production of coal. Lands and water eligible for reclamation are those that were mined or affected by mining and abandoned or left in an inadequate reclamation status prior to August 3, 1977, and for which there is no continuing reclamation responsibility under State/Tribal or Federal Law.

Title IV provides that if the Secretary determines that a State or Tribe has developed and submitted a program for reclamation of abandoned mines and has the ability and necessary State or Tribal legislation to implement the provisions of Title IV, the Secretary may approve the State or Tribal program and grant to the State or Tribe exclusive responsibility and authority to implement the provisions of the approved program.

OSMRE has received a proposed AMLR plan from the Navajo Tribe. The purpose of this submission is to determine both the intent and capability to assume responsibility for administering and conducting the provisions of SMCRA and OSMRE's Abandoned Mine Land Reclamation (AMLR) Program (30 CFR Chapter 7, Subchapter R) as published in the *Federal Register* (FR) on June 30, 1982, 47 FR 28574-28604.

This notice describes the nature of the proposed program and sets forth information concerning public participation in the Secretary's determination of whether or not the submitted plan may be approved. The public participation requirements for the consideration of a State or Tribal AMLR Plan are found in 30 CFR 884.13 and 884.14. Additional information may be found under corresponding sections of the preamble to OSMRE's AMLR Program Rules published October 25, 1978 (43 FR 49932-49952).

The receipt of the Navajo Tribe's Plan is the first step in the process that will result in the establishment of a comprehensive program for the reclamation of abandoned mine lands on the Navajo Tribal Lands.

By submitting a proposed Plan, the Navajo Tribe has indicated that it wishes to be primarily responsible for this program. If the submission, as hereafter modified, is approved by the Secretary, the Navajo Tribe will have primary responsibility for the

reclamation of abandoned mine lands on Navajo Tribal Lands.

The Department intends to continue to discuss the Navajo Tribe's proposed Plan with representatives of the Tribe throughout the review process. All contacts between OSMRE personnel and representatives of the Tribes will be conducted in accordance with OSMRE's guidelines on contacts with States published September 19, 1979, at 44 FR 54444.

II. Discussion of Proposed Plan

The Navajo Plan is designed to apply the provisions of Title IV of the Surface Mining Control and Reclamation Act (SMCRA) of 1977 to reclamation of abandoned mines on the Navajo Tribal Lands. The Plan includes discussions of criteria for selecting and ranking proposed projects; standards for acquiring, managing, and disposing of land under the AMLR program; public participation policy; and descriptions of proposed projects. The existing environment on the Tribal lands is also described in the Plan.

The following constitutes a summary of the contents of the Navajo Tribe's Reclamation Plan submission:

(a) Designation of authorized Tribal Agency to administer the program.

(b) Tribes's General Counsel's opinion that the designated Agency has the legal authority to operate the program in accordance with the requirements of Title IV of SMCRA, 30 CFR Chapter 7, Subchapter R, and the Tribal Reclamation Plan.

(c) Description of the policies and procedures to be followed in conducting the program including:

- (1) Goals and objectives;
- (2) Project ranking and selection procedures;
- (3) Coordination with other reclamation programs;
- (4) Land acquisition, management, and disposal;
- (5) Reclamation on private land;
- (6) Rights of entry; and
- (7) Public participation in the program.

(d) Description of the administrative and management structure to be used in the program including:

- (1) Description of the organization of the designated agency and its relationship to other organizations that will participate in the program;
- (2) Personnel staffing policies;
- (3) Purchasing and procurement systems and policies; and
- (4) Description of the accounting system including specific procedures for operation of the reclamation fund.

(e) Description of the reclamation activities to be conducted under the Tribal Reclamation Plan discussing the

known or suspected eligible lands and waters within the Tribal lands and including:

(1) A map showing the general location of known or suspected eligible lands and waters;

(2) A description of the problems occurring on these lands;

(3) How the Plan proposes to address each of the problems;

(f) Description of the conditions prevailing on the different geographic areas of the Tribal lands where reclamation is planned, including:

- (1) The economic base;
- (2) Significant esthetic, historic or cultural, and recreational values; and
- (3) Endangered and threatened plants, fish, and wildlife and their habitat.

The Navajo Tribe has also requested authority to assume responsibility for emergency reclamation activities. Guidelines for assumption of this responsibility are published in the *Federal Register*, 47 FR 42729 (September 29, 1982).

The Navajo Tribal Reclamation Plan for Abandoned Mine Lands can be approved if:

1. The Secretary finds that the public has been given adequate notice and opportunity to comment, and the record does not reflect major unresolved controversies.

2. Views of other Federal agencies have been solicited and considered.

3. The Tribe has the legal authority, policies and administrative structure to carry out the Plan.

4. The Plan meets all the requirements of the OSMRE AMLR Program provisions.

5. It is determined that the Plan is in compliance with all applicable Tribal and Federal laws and regulations.

Dated: November 4, 1987.

Brent T. Wahlquist,

Assistant Director, Program Policy, Office of Surface Mining Reclamation and Enforcement.

[FR Doc. 87-27395 Filed 12-3-87; 8:45 am]

BILLING CODE 4310-05-M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD 6010.8-R]

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Participation Requirements for Residential Treatment Centers (RTC)

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed amendment of rule.

SUMMARY: This proposed rule will revise DoD 6010.8-R (32 CFR Part 199) which implements the Civilian Health and Medical Program of the Uniformed Services. The rule clarifies participation requirements and establishes a new reimbursement system for payment of RTC care while providing safeguards to ensure continued benefit access and quality of care. The rule will also ensure that CHAMPUS beneficiaries are not discriminated against solely on the basis of program payment methodology. The new payment system will provide reasonable reimbursement for high quality care for CHAMPUS beneficiaries.

DATE: Written public comments must be received on or before January 4, 1988.

ADDRESS: Office of the Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS), Aurora, Colorado 80045-6900.

FOR FURTHER INFORMATION CONTACT: David E. Bennett, Office of Program Development, OCHAMPUS, Aurora, Colorado 80045-6900, telephone (303)-361-8608.

SUPPLEMENTARY INFORMATION: In FR Doc. 77-7834, appearing in the *Federal Register* on April 4, 1977 (42 FR 17972), the Office of the Secretary of Defense published its regulation, DoD 6010.8-R, "Implementation of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)," as part 199 of this title. DoD Regulation 6010.8-R was reissued in the *Federal Register* on July 1, 1986 (51 FR 24008).

Background

An RTC is a facility (or distinct unit of a facility) organized and professionally staffed to provide residential treatment for mental disorders to children and adolescents under the age of 21 who have sufficient intellectual potential to respond to active psychiatric treatment. Residential treatment is a specific level of care to be differentiated from acute, intermediate and long-term hospital care, where the least restrictive environment is maintained to allow for normalization of the patient's surroundings. The coverage extends to services and supplies provided by RTCs including room and board, patient assessment, diagnostic services, psychological evaluation tests, treatment of the medical disorder for which the patient is admitted, and other necessary medical care as required.

Present agency actions have evolved from a long history of CHAMPUS problems and concerns over the RTC benefit dating back to 1974, when the

Department of Defense came under heavy criticism for not adequately monitoring the quality of care in RTCs. In response to this criticism DoD secured the assistance of the National Institute of Mental Health (NIMH) and the American Psychiatric Association (APA) to help develop an independent, authoritative quality control and interdisciplinary peer review system for the RTC benefit.

The DoD, with the assistance of the NIMH, devoted extensive effort to monitoring RTCs. Standards were developed, published, and implemented. On-site visits, both announced and unannounced, were made to inspect RTCs housing CHAMPUS-supported children.

Three years later, in 1977, the number of CHAMPUS child-beneficiaries in RTCs had plummeted from a one-time peak of nearly 3,000 to about 200. The number of CHAMPUS-approved centers reimbursed for RTC treatment was down to fewer than 100 from more than 1,000 in 1973. The total cost of the benefit to taxpayers had dropped from \$13.5 million in 1973 to less than \$4 million in three years.

This dramatic turnaround was not accomplished by arbitrarily cutting benefits. Rather, it was largely the result of a case-by-case peer review system, numerous on-site visits to enforce the CHAMPUS standards, prescreening and preauthorization for payment, and contractual participation agreements with each facility. On January 10, 1977, CHAMPUS regulation DoD 6010.8-R (32 CFR Part 199) was issued which specifically outlined the criteria for participation of RTCs in the CHAMPUS program. This included a requirement for accreditation by the Joint Commission on Accreditation of Hospitals (JCAH) under the Commission Standards for Psychiatric Facilities Serving Children and Adolescents and that the RTC enter into a participation agreement with OCHAMPUS requiring the RTC to comply with CHAMPUS Standards for RTCs. The specifics of the participation agreement were not included in the Regulation. Since then, OCHAMPUS has continued to be criticized for what has been described as inadequate controls over the cost of care rendered by RTCs.

On November 14, 1979, the Defense Audit Service issued a report on the management and administration of psychiatric benefits under CHAMPUS. Findings contained in the report included: (1) Improvements were needed in the management of funding of psychiatric care; (2) rates charged by RTCs were not reasonable and had no basis; (3) collection of the beneficiaries

cost-share was not implemented in accordance with the Regulations, and CHAMPUS paid for the under-collected cost-share amounts through higher charges; and (4) no control over provider rates existed.

Attempts were made to resolve these problems including, on July 31, 1981, a proposal to eliminate RTCs as authorized providers under CHAMPUS for new admissions on and after October 1, 1981. On December 10, 1981, this proposal was withdrawn due to Congressional and public response requesting that CHAMPUS maintain RTC care.

Under the terms of the participation agreement used in the past, RTCs are limited to reasonable charges not to "exceed the provider's most-favorable rate to any other patient, agency, or organization." As a result of audits conducted on the top ten RTCs over a three-year period, it became increasingly evident that many RTCs were not billing at their most-favored rate. The findings of these audits reflected serious deficiencies in OCHAMPUS' ability to adequately monitor RTC costs and charging practices, and the likelihood that substantial over-payment for RTC care in general existed under the current system. These audits, along with subsequent appeals, also demonstrated that the prior participation agreement did not clearly establish the RTC's responsibilities. OCHAMPUS' lack of control over RTC charges was further challenged by the January 1, 1983, statutory implementation of the 60-day inpatient mental health limitation which limited inpatient psychiatric hospital care to no more than 60 calendar days of care per year. Since RTCs were specifically exempted from the limitation, CHAMPUS experienced a dramatic increase in the number of hospital-based RTCs and a corresponding increase in program expenditures. Annual expenditures for RTC care have increased from approximately \$20 to \$25 million prior to 1983 to over \$45 to \$50 million currently estimated.

On September 14, 1984, final regulations amending 32 CFR Part 199 were published in the *Federal Register* (49 FR 36087-36095), revising the requirements for RTC participation in the CHAMPUS program. The primary purposes of the revisions were: (1) To enhance the quality of RTC care available to CHAMPUS beneficiaries; (2) to increase the accountability of all RTCs to ensure only medically necessary and appropriate care was provided; and (3) to control costs of care

in RTCs. The revised mental health regulation provided much more detail concerning the requirements of the participation agreement and held the RTC's Medical Director accountable for all patient care. Moreover, the Regulation specifically required the RTC to "accept payment for its services based upon an allowable-cost rate acceptable to the Director, OCHAMPUS, or such other method as determined by the Director, OCHAMPUS." This established the Director's authority to implement a new payment methodology for reimbursement of RTCs, the authority for which has existed since the original publication of the CHAMPUS regulation in 1977.

Based upon previous audit findings and the specific provisions of the revised CHAMPUS regulation authorizing the Director to establish methods of RTC reimbursement, a study was initiated by OCHAMPUS to evaluate alternative reimbursement systems for care in RTCs serving children and adolescents. The purpose of this study was to develop recommendations for a uniform prospective payment system that would control costs for RTC care, ensure continued high quality and access for CHAMPUS beneficiaries, and provide relatively simple administration. The study was intended to provide background, and a definitive proposal with supporting rationale.

The report found that RTC rates were widely disparate and could not be related to any valid basis to justify the range of charges, particularly those at the high end of the spectrum. The final report recommended that CHAMPUS adopt a RTC payment methodology based upon a prospective per diem rate system with a ceiling amount.

From these recommendations and a detailed analysis of RTC charge and utilization data, a reimbursement methodology was developed for determining individual all-inclusive per diem rates for each RTC and ultimately a payment cap amount.

The all-inclusive per diem rate will encompass the RTC's daily charge for RTC inpatient care and all mental health treatment determined necessary and rendered as part of the treatment plan established for the patient and accepted by OCHAMPUS. This includes all individual and group psychotherapy rendered by the RTC, family therapy rendered to the parents of the RTC patient, whether or not the patient is physically present, collateral visits with individuals other than the RTC patient determined necessary in order to gather information or implement treatment

goals for the patient, and all other ancillary services provided by the RTC.

The changes in the RTC reimbursement methodology are intended, in part, to increase the RTC's accountability for ensuring a high quality of care. The all-inclusive rate provides a mechanism by which they can achieve the control necessary to meet this increased accountability. Each RTC will be completely free to determine how it will choose to provide services, either through its own staff or through arrangements with professional and ancillary providers in the community. OCHAMPUS' intent has never been to exclude professional providers from caring for patients in RTCs. It is, rather, to design a reimbursement methodology that reflects the philosophy that residential treatment is a total therapeutic program. This philosophy and resulting reimbursement design can be validated by the fact that the majority of RTCs currently bill on an all-inclusive basis. The rate established for each individual RTC will reflect both the institutional and professional charges which were submitted per an OCHAMPUS request of October 18, 1985. The RTCs were specifically instructed to submit the charges of individual mental health providers which were not employed by or contracted with their facility, along with the frequency of their occurrence.

On April 25, 1986, all currently participating RTCs were notified in writing of their individual rates, provided with the rationale for the rates, and provided two copies of the final participation agreements for signature and return by June 1, 1986. Sponsors of patients currently in the RTCs were also notified of the new agreements, as were interested Congressional offices and organizations and the Surgeons General of the Uniformed Services.

By July 1, 1986, 74 agreements had been signed and returned to OCHAMPUS (89 percent of the mailed participation agreements). However, on June 30, 1986, OCHAMPUS was enjoined from implementing the proposed RTC payment methodology by the United States District Court, District of Colorado. The temporary order was issued based upon a civil action filed by the National Association of Psychiatric Treatment Centers for Children (NAPTCC); the American Association of Children's Residential Centers; Coalition of Concerned Physicians of San Diego; and Dori Nanry, on behalf of herself and her minor. The plaintiffs sought a preliminary injunction to the implementation of the new participation agreement (reimbursement

methodology) based on the assertion that the participation agreement was a rule and as such was subject to the procedural requirements of the Administrative Procedure Act (APA). They felt that the participation agreement was formed in a procedurally invalid manner because OCHAMPUS failed to consult with appropriate agencies, as required by statute, when creating the agreement.

On March 3, 1987, a copy of the decision rendered by the United States District Court, District of Colorado, dated February 27, 1987, was received by OCHAMPUS. It was the Court's finding that OCHAMPUS failed to comply with the rulemaking provisions of the Administrative Procedures Act (APA) and, therefore, was enjoined from proceeding to implement the revised participation agreement and reimbursement system until such time that the requirements of the APA were met.

The District Court's decision has been appealed to the Tenth Circuit Court of Appeals. OCHAMPUS believed at the time it issued the new RTC participation agreement that it had the requisite authority and that it was proper to do so. OCHAMPUS still believes its position is correct, however, pending the resolution of the appeal, OCHAMPUS is complying with the District Court's decision. The proposed amendment is being published in compliance with the Court's decision.

Until there is a decision in the appeal, it will not be known if the District Court's decision will be reversed. In the event that the District Court's decision is reversed, OCHAMPUS intends to recoup any payments to RTCs in excess of the payments that would have been made had the District Court not enjoined the implementation of the payment provisions.

Whether the NAPTCC District Court decision is upheld on appeal or reversed, the effective date of a final rule on reimbursement provisions for RTC care will be applicable. Any recoupment, if the District Court is reversed, will be from July 1, 1986 (the original effective date of the new participation agreement), to the effective date of the proposed rule.

OCHAMPUS has developed an interim RTC participation agreement. This agreement clarifies how current RTCs may be reimbursed and is used to recognize RTCs applying for CHAMPUS authorization. Since the old participation agreement is no longer considered to meet the needs of the Government and OCHAMPUS is enjoined from using the new

participation agreement, there has been no way to recognize new RTCs and no participation agreement to replace the one the Court found objectionable. The interim agreement is modeled after the "new" participation agreement with the exception of the payment provisions. The most-favored rate provision is substituted for the prospective per diem capped amount.

Pursuant to the Court's decision, OCHAMPUS is proceeding with a general notice of proposed rulemaking which will allow interested persons an opportunity to participate in the rulemaking process through submission of written views or arguments regarding the new RTC reimbursement methodology.

The major provisions of the proposed RTC reimbursement system are being incorporated into the CHAMPUS regulation, along with the safeguards needed to ensure continued benefit access and quality of care. A provision is also being included which will ensure that CHAMPUS beneficiaries are not discriminated against solely on the basis of program payment methodology.

Rate Determination

1. RTCs Participating in CHAMPUS During Base Period

The per diem rate for an RTC participating in the CHAMPUS during the base period of March 1, 1984, through February 28, 1985, will be based on the actual charging practices during that 12 month period. This base period was chosen: (1) Because it corresponded to the base period used in our previous study; and (2) because the drastic increase in RTC charges in the last two years could not be justified by national health care statistics. The individual RTC rate will be the lower of either the CHAMPUS rate in effect on March 1, 1985, or the rate high enough to cover at least one-third of the total patient days of care provided by the RTC during the 12 months ending February 28, 1985. Under either methodology, the rate will be subject to a maximum cap. These rates will be adjusted by an inflation factor reflecting the national Consumer Price Index for Urban Wage Earners (CPI-U) for medical care for the 24-month period ending February 28, 1987.

2. RTCs New to CHAMPUS After February 28, 1985

For RTCs new to the CHAMPUS program, one of the following two alternative methods will be used in determining their individual rates:

A. The rates of RTCs which were in operation during the base period (March 1, 1984 through February 28, 1985) will

be calculated based on the actual charging practices of the RTC during the 12 months ending February 28, 1985. The RTC's rate will be the lower of either the rate high enough to cover at least one-third of its total patient days of care provided during the 12 months and inflated by the CPI-U, or the OCHAMPUS determined, capped per diem.

B. The rates for RTCs which began operation after February 28, 1985, will be based on the actual charging practices during their first 6 to 12 consecutive months, with 6 months being the minimum time in operation for certification under the CHAMPUS program. The rates would be calculated the same as in A above except a different base period would be used and the rate would be adjusted by an appropriate CPI-U factor for medical care to bring it forward to February 28, 1987.

The CPI-U inflation factor is being used to update the RTC's individual rates, as well as the capped amount, because of the anticipated delay in their implementation. The revised capped amount for RTC care will be \$266 per day.

All routine and special education costs are excluded from reimbursement except in individual cases where appropriate education is not available through other local, state, or federal agencies. Under the new educational provisions, RTCs will have greater responsibility for ensuring that beneficiaries take maximum advantage of their rights to a free and appropriate public education.

A provision is also being incorporated into the Regulation regarding therapeutic absences. Under this provision, CHAMPUS will continue payment at the full per diem rate for approved absences not exceeding three calendar days. Those in excess of this time frame will be paid at 75 percent of the established daily charge beginning with the fourth day of absence.

There will be a grandfathering period for those CHAMPUS patients who are receiving care in an RTC at the time the new reimbursement methodology is adopted. To ensure continued care of these beneficiaries, payment at the current rate, including separate payment for professional services, will continue for all beneficiaries admitted prior to the implementation date, until discharge, transfer or until two months of care have elapsed, whichever occurs first, or as otherwise required by law.

Clarifying language is being adopted in the Regulation to further define the level of care provided in a RTC and to establish an appropriate age limit for

beneficiaries receiving care in this type of facility.

We feel that the new participation requirements will not have a significant economic impact on either the institutional or professional components of RTC treatment. The prospective reimbursement methodology was designed to take into account the individual circumstances of each RTC. All participating RTCs were asked to provide specific information concerning their charges, both professional and institutional. The professional charge data represented an average overall charge based on estimated utilization patterns for each facility. The all-inclusive nature of this new payment methodology will not prevent the treatment of RTC patients by community practitioners. The only change will be that community practitioners will look directly to the RTC for reimbursement rather than CHAMPUS. The all-inclusive rate was adopted to ensure that professional services are not duplicated and are provided in accordance with an established CHAMPUS standards.

Less than 0.13 percent of CHAMPUS institutional providers and less than 0.04 percent of CHAMPUS individual professional providers will be affected by this amendment. Although several RTCs have expressed concerns over the new system and the potential impact on their method of doing business, approximately 80 percent of the currently approved RTCs have indicated that they will continue their participation in the program. It is also estimated that two-thirds of the CHAMPUS approved RTCs already bill their services on an all-inclusive basis. Since the net impact on both institutional and professional components of RTC care will not be significant, the Secretary certifies that this proposed rule, if promulgated as a final rule, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. It is not, therefore, a "major rule" under Executive Order 12291.

This amendment is being published in the **Federal Register** for proposed rulemaking at the same time it is being coordinated within the Department of Defense and with other interested agencies so that consideration of both internal and external comments and publication of the final rule can be expedited.

List of Subjects in 32 CFR Part 199

Health insurance, Military personnel, Handicapped.

Accordingly, 32 CFR, Part 199, is proposed to be amended as follows:

1. The authority citation for Part 199 continues to read as follows:

Authority: 10 U.S.C. 1079, 1086, 5 U.S.C. 301.

2. Section 199.2(b) is amended by adding definitions for "all-inclusive per diem rate," "capped rate," and "mental health therapeutic absence" in alphabetical order as follows:

§ 199.2 Definitions.

(b) *Specific definitions.*

All-Inclusive Per Diem Rate. The OCHAMPUS determined rate that encompasses the daily charge for inpatient care and all other treatment determined necessary and rendered as part of the treatment plan established for a patient, and accepted by OCHAMPUS.

Capped Rate. The maximum per diem or all-inclusive rate that CHAMPUS will allow for care.

Mental Health Therapeutic Absence. A therapeutically planned absence from the inpatient setting. The patient is not discharged from the facility and may be away for periods of several hours to several days. The purpose of the therapeutic absence is to give the patient an opportunity to test his or her ability to function outside the inpatient setting before the actual discharge.

3. Section 199.4 is amended by revising paragraph (g)(6) to read as follows:

§ 199.4 Basic Program benefits.

(g) *Therapeutic absences.* Therapeutic absences from an inpatient facility, except when such absences are specifically included in a treatment plan approved by the Director, OCHAMPUS, or a designee. For cost-sharing provisions refer to § 199.14, paragraph (e)(3).

4. Section 199.6 is amended by revising paragraphs (b)(4)(vii) introductory text, (b)(4)(vii)(A)(1), and (b)(4)(vii)(A)(4), by adding a new paragraph (b)(4)(vii)(A)(5), by removing the note under (b)(4)(vii)(B), and by adding new paragraphs (b)(4)(vii)(C)(6) and (b)(4)(vii)(D).

§ 199.6 Authorized providers.

(b) * * *

(4) * * *

(vii) *Residential treatment centers.* A residential treatment center (RTC) is a facility or distinct part of a facility that provides to children and adolescents under the age of 21, a total, 24 hour therapeutically planned group living and learning situation where distinct and individualized psychotherapeutic interventions can take place. Residential treatment is a specific level of care to be differentiated from acute, intermediate and long term hospital care, where the least restrictive environment is maintained to allow for normalization of the patient's surroundings. The RTC must be both physically and programmatically distinct if it is a part or subunit of a larger treatment program. An RTC is organized and professionally staffed to provide residential treatment of mental disorders to children and adolescents who have sufficient intellectual potential to respond to active treatment (that is, for whom it can reasonably be assumed that treatment of the mental disorder will result in an improved ability to function outside the RTC), for whom outpatient, partial hospitalization or other level of inpatient treatment is not appropriate, and for whom a protected and structured environment is medically or psychologically necessary.

(A) * * *

(1) Be accredited by the Joint Commission on Accreditation of Hospitals under the Consolidated Standards Manual for Child, Adolescent, and Adult Psychiatric, Alcoholism, and Drug Abuse Facilities and Facilities Serving the Mentally Retarded.

(4) Have entered into a Participation Agreement with OCHAMPUS within which the RTC agrees, in part, to:

(i) Render residential treatment center inpatient services to eligible CHAMPUS beneficiaries in need of such services, in accordance with the participation agreement and the OCHAMPUS regulation.

(ii) Accept payment for its services based upon the methodology provided in § 199.14, paragraph (e) or such other method as determined by the Director, OCHAMPUS;

(iii) Accept the CHAMPUS all-inclusive per diem rate as payment in full and collect from the CHAMPUS beneficiary or the family of the CHAMPUS beneficiary only those amounts that represent the beneficiary's liability, as defined in § 199.4, and charges for services and supplies that are not a benefit of CHAMPUS;

(iv) Make all reasonable efforts acceptable to the Director, OCHAMPUS, to collect those amounts which represent the beneficiary's liability, as defined in § 199.4;

(v) Comply with the provisions of § 199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to CHAMPUS;

(vi) Submit claims for services provided to CHAMPUS beneficiaries at least every 30 days. If claims are not submitted at least every 30 days, the RTC agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by CHAMPUS;

(vii) Designate an individual who will act as liaison for CHAMPUS inquiries. The RTC shall inform OCHAMPUS in writing of the designated individual;

(viii) Furnish OCHAMPUS with cost data certified to by an independent accounting firm or other agency as authorized by the Director, OCHAMPUS;

(ix) Grant the Director, OCHAMPUS, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records to determine the quality and cost-effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review includes, but is not limited to:

(aa) Examination of fiscal and all other records of the RTC which would confirm compliance with the participation agreement and designation as an authorized CHAMPUS RTC provider;

(bb) Conducting such audits of RTC records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;

(cc) Examining reports of evaluations and inspections conducted by federal, state and local government, and private agencies and organizations;

(dd) Conducting on-site inspections of the facilities of the RTC and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required.

(ee) Audits conducted by the United States General Accounting Office.

(5) Be licensed and operational for a minimum period of six months.

(C) * * *

(6) The child's admission to the RTC is authorized by CHAMPUS.

(D) Under the terms of the participation agreement, RTCs must provide the following safeguards for continued benefit access and quality of care:

(1) Assure that any and all eligible beneficiaries receive care which complies with standards in paragraphs (b)(4)(vii)(A) (1) through (5) and (b)(4)(vii)(C);

(2) Provide inpatient services to CHAMPUS beneficiaries in the same manner it provides inpatient services to all other patients;

(3) Not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment.

* * * * *

5. Section 199.14 is amended by redesignating paragraphs (e), (f), and (g) as (f), (g), and (h), adding new paragraph (e), and by redesignating newly redesignated paragraph (f)(2) as (f)(3), and adding new paragraph (f)(2) to read as follows:

§ 199.14 Provider reimbursement methods.

* * * * *

(e) *Reimbursement of residential treatment centers.* The CHAMPUS rate is the per diem rate that CHAMPUS will authorize for all mental health services rendered to a patient and the patient's family as part of the total treatment plan submitted by a CHAMPUS-approved RTC, and approved by OCHAMPUS.

(1) The all-inclusive per diem rate for RTCs operating or participating in CHAMPUS during the base period of March 1, 1984, through February 28, 1985, will be the lowest of the following conditions:

(i) The CHAMPUS rate paid to the RTC for all-inclusive services as of March 1, 1985, adjusted to include an increase reflecting the national Consumer Price Index for Urban Wage Earners (CPI-U) for medical care for the 24-month period ending February 28, 1987; or

(ii) The per diem rate accepted by the RTC from any other agency or organization (public or private) or individual that is high enough to cover one-third of the total patient days during the 12-month period ending February 28, 1985, adjusted by the CPI-U; or

(iii) An OCHAMPUS determined capped per diem set at the 80th percentile of all established CHAMPUS RTC rates nationally, weighted by total CHAMPUS days provided at each rate during the base period discussed in paragraph (e)(1) of this section.

(2) The all-inclusive per diem rates for RTCs which began operation after February 28, 1985, will be calculated based on the lower of the per diem rate accepted by the RTC that is high enough to cover one-third of the total patient days during their first 6 to 12 consecutive months of operation adjusted by the CPI-U, if appropriate, based upon the base period used or the OCHAMPUS determined capped amount.

(3) The first three days of each approved therapeutic absence will be reimbursed at 100 percent of the CHAMPUS determined all-inclusive per diem rate. Beginning with day four, reimbursement will be at 75 percent of that rate.

(4) All educational costs, whether they include routine education or special education costs, are excluded from reimbursement except when appropriate education is not available from or not payable by a cognizant public entity.

(i) The RTC shall exclude educational costs from its daily costs.

(ii) The RTC's accounting system must be adequate to assure CHAMPUS is not billed for educational costs.

(iii) The RTC may request payment of educational costs on an individual case basis from the Director, OCHAMPUS, or designee, when appropriate education is not available from or not payable by a cognizant public entity. To qualify for reimbursement of educational costs in individual cases, the RTC shall comply with the application procedures established by the Director, OCHAMPUS, or designee, including, but not limited to, the following:

(A) As part of its admission procedures, the RTC must counsel and assist the beneficiary and the beneficiary's family in the necessary procedures for assuring their rights to a free and appropriate public education.

(B) The RTC must document any reasons why an individual beneficiary cannot attend public educational facilities and, in such a case, why alternative educational arrangements have not been provided by the cognizant public entity.

(C) If reimbursement of educational costs is approved for an individual beneficiary by the Director, OCHAMPUS, or designee, such educational costs shall be shown separately from the RTC's daily costs on the CHAMPUS claim.

(D) If the RTC fails to request CHAMPUS approval of the educational costs on an individual case, the RTC agrees not to bill the beneficiary nor the beneficiary's family for any amounts disallowed by CHAMPUS. Requests for payment of educational costs must be

referred to the Director, OCHAMPUS, or designee for review and a determination of the applicability of CHAMPUS benefits.

(5) Any changes or future adjustments to the RTC rates will be at the discretion of the Director, OCHAMPUS, or designee.

* * * * *

(f) * * *

(2) *All-inclusive rate.* Claims from individual health-care professional providers for services rendered to CHAMPUS beneficiaries residing in an RTC that is either being reimbursed on an all-inclusive per diem rate, or is billing an all-inclusive per diem rate, shall be denied. Reimbursement for individual professional services is included in the rate paid the institutional provider.

* * * * *

Linda Bynum,
Alternate OSD Federal Register Liaison
Officer, Department of Defense.

December 1, 1987.

[FR Doc. 87-27853 Filed 12-3-87; 8:45 am]

BILLING CODE 3810-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 69

[CGD 87-015a]

Delegation of Authority To Measure Vessels

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish the criteria necessary for an organization to qualify as a delegate to formally measure U.S. commercial, recreational, and public non-combatant vessels. This rulemaking would implement the statutory provision authorizing the Coast Guard to delegate measurement functions, yet ensure high quality service to the maritime industry.

DATE: Comments must be received on or before February 2, 1988.

ADDRESSES: Comments may be mailed to Commandant (G-CMC/21) (CGD 87-015a), U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593-0001. Comments will be available for examination or copying at the Office of the Marine Safety Council, Room 2110, at the above address, between 8 a.m. and 3 p.m., Monday through Friday, except holidays. The telephone number is (202) 267-1477.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph T. Lewis, Merchant Vessel Inspection and Documentation Division, (202) 267-2992.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Transportation (Coast Guard) is authorized by statute (46 U.S.C. 14103) to delegate to a "qualified person" the authority to measure, and to issue certificates of measurement for, vessels that are required or eligible to be documented as a vessel of the United States. As a result, the Coast Guard published a Final Rule (52 FR 15947; May 1, 1987) which delegated to the American Bureau of Shipping (ABS) the authority to perform U.S. formal tonnage measurement services for commercial, recreational, and public non-combatant vessels. In the preamble to that rule, the Coast Guard indicated its intention to extend this delegation to other qualified organizations once it had established criteria for eligibility. The objective of the present proposal is to establish those criteria.

Drafting Information

The principal persons involved in drafting this rule are Mr. Joseph T. Lewis, Project Manager, and Mr. Stephen H. Barber, Project Counsel, Office of Chief Counsel.

Background

Vessels that measure five net tons or greater are either required or eligible to be documented as a vessel of the United States. Before a vessel may be documented, it first must be measured to establish its tonnage. Traditionally, vessel measurement has been exclusively a governmental service and was provided free of charge. However, with the passage of Pub. L. 99-509, the Coast Guard is authorized to charge a fee for measurement services or, if it chooses, to delegate measurement authority to the private sector. On May 1, 1987 (52 FR 15947), the Coast Guard decided to delegate this authority to the American Bureau of Shipping with the proviso that the Coast Guard would develop criteria for delegation to other similar organizations. The purpose of this rulemaking is to develop those criteria. This delegation is in keeping with the Coast Guard's policy to discontinue its formal tonnage measurement services for U.S. commercial, recreational, and public non-combatant vessels and to transfer these services entirely to qualified private measurement organizations. Delegation of authority to additional organizations should assure optimum responsiveness to the public and

enhance competition in the marketplace, while continued oversight by the Coast Guard should ensure correct and consistent application of measurement laws and regulations.

Discussion of the Proposed Rule

This proposed rulemaking would establish a new 46 CFR 69.01-20 that lists the basic requirements for delegation of the authority to provide formal tonnage measurement services for commercial, recreational, and public non-combatant vessels of the United States.

Pub. L. 99-509 provides that the International Convention on Tonnage Measurement of Ships, 1969, will become the primary system used to formally measure all U.S. vessels of 79 feet or longer, once implementing regulations are promulgated. The requirements of this system must be applied consistently both nationally and internationally. This legislation also retains the standard and optional dual tonnage measurement systems for vessels of any size for use in regulatory applications, such as vessel inspection and manning.

This proposed rulemaking is designed to ensure that tonnage measurement services identical to those previously provided by the Coast Guard continue to be available to the public. In order to best serve the needs of the U.S. marine industry domestically and to meet our international obligations, a delegated organization must maintain a tonnage measurement staff capable of providing U.S. formal tonnage measurement and remeasurement services for vessels domestically and internationally (proposed § 69.01-20(b)(3)). By limiting delegations to organizations with this capability, the burden of vessel owners having to submit duplicate information to different organizations would be eliminated. At the same time, organizations which operate globally are less subject to local pressures than are organizations limited to particular clients or geographic areas.

The Coast Guard has determined that organizations best meeting these qualifications are ship classification organizations that are a full member of the International Association of Classification Societies (IACS) (proposed § 69.01-20(b)(1)). IACS member organizations (which includes the American Bureau of Shipping) regularly provide a broad spectrum of regulatory services to the marine industry. They establish and administer standards for the design, construction, and periodic survey of merchant vessels, classify merchant vessels, certify vessel structural and mechanical fitness, assign

load lines, and retain highly qualified marine technical staffs. U.S. organizations that are a member of IACS offer tonnage measurement services similar to the services traditionally provided by the Coast Guard. These organizations have been delegated authority by many other nations to measure vessels. Tonnage certificates issued by full member IACS organizations are recognized and accepted internationally. Classification societies maintain a close working relationship with the Coast Guard in many activities and are not solely dependent on tonnage measurement. This relationship, therefore, should provide the Coast Guard with the control necessary to ensure consistent application of tonnage measurement statutory and regulatory requirements. Proposed § 69.01-20(b)(2) would require that a candidate for delegation be a U.S. organization incorporated under the laws of the United States or a state of the United States. This is necessary primarily to ensure ready access to measurement files and to provide appropriate oversight over measurement operations.

Proposed § 69.01-20(b)(4) would require delegate organizations to maintain a tonnage measurement staff that has practical experience in measuring U.S. vessels under the tonnage measurement rules in 46 CFR 69.03 and 69.15 and under the International Convention on Tonnage Measurement of Ships, 1969. These provisions would ensure that the organization is capable of providing all measurement services that normally are required by U.S. vessel owners.

Proposed § 69.01-20(c) describes the procedure for applying for a delegation of authority and lists the information needed to determine eligibility.

Proposed § 69.01-20(d) concerns the Memorandum of Agreement (MOA) that eligible applicants must enter into before being delegated measurement authority. The items specified in paragraph (d) relate to defining the roles and responsibilities of the parties and ensuring that the Coast Guard retains adequate opportunity for oversight. Proposed paragraph (d)(3) would prohibit organizations from measuring and certifying vessels for which one of their employees or contractors acted as tonnage consultant. Tonnage consultants assist in the design of a vessel to achieve a desired tonnage. As tonnage consultation was not provided by the Coast Guard for reasons of potential conflict of interest, the Coast Guard is proposing to apply the same policy to organizations delegated its

measurement and certification functions. Proposed paragraph (d)(4)(i) would require the organization to accept all requests for measurement services without discrimination and without regard to the vessel's location. If performing these services in the particular location of the vessel would be a violation of United States law or the law of the jurisdiction in which the vessel is located, the organization may deny the request. Proposed paragraph (d)(4)(vii) is a catch-all provision and would cover additional administrative provisions, such as procedures for the maintenance and accessibility of tonnage files and the preparation of workload reports. In addition, paragraph (d)(4)(vii) provisions could describe Coast Guard functions, such as processing appeals, interpreting regulations, approving water-ballast justifications, providing tonnage calculation information when available, and providing policy information to assure consistent application of the laws and regulations.

Proposed § 69.01-20(e) would require that all organizations delegated authority under this rule be added to the list of measurement sources in 46 CFR 69.01-11. Section 69.01-11 has been revised recently to include the American Bureau of Shipping as a measurement source (52 FR 15947; May 1, 1987).

Regulatory Evaluation

This proposal is considered to be non-major under Executive Order 12291 and non-significant under Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979). The economic impact of this proposal has been found to be so minimal that further evaluation is unnecessary.

This proposal is administrative in nature and would transfer certain measurement services from the Coast Guard to qualified private organizations without substantive change. Traditionally, the formal measurement functions being delegated were provided free of charge by the Coast Guard. Pub. L. 99-509 now authorizes the Coast Guard to charge a fee for these services based upon actual costs to the Government or, if it chooses, to delegate to the private sector the authority to provide these services. Instead of handling these services itself and charging a fee, the Coast Guard has determined that it is in the best interests of the Government and the public to delegate this function to the private sector.

Based on fees charged by the current delegate, a typical cost for formal measurement and certification is

approximately \$600 for a vessel measuring less than 1,000 gross tons and \$7,500 for a vessel measuring 50,000 gross tons. Tonnage measurement is usually a one-time expenditure and its costs represent a small proportion of the value of a vessel. During 1987, less than 1,000 vessels required formal measurement. The Coast Guard will continue to measure vessels under the simplified measurement system, which during 1987, amounted to more than 17,000 vessels.

The cost of preparing an application for delegation would vary from applicant to applicant but, in general, the information needed to complete an application is readily available within the applicant organization. The costs, therefore, for application preparation and information gathering are estimated to be less than \$2,600 per application.

Regulatory Flexibility Act

This proposal provides for the delegation of tonnage measurement by publishing qualifications that organizations must meet in order to be delegated this authority. No new application costs, burdens, or procedures would be imposed upon vessel owners. Organizations requesting measurement authority would be required to submit basic information to the Coast Guard relating to their capability to perform measurement services for the marine industry. Because eligible organizations would have to provide worldwide services, they would tend to be large corporations.

Because the impact of this proposal is expected to be minimal, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)) that this proposal, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This proposed rulemaking contains information collection requirements in § 69.01-20. They have been submitted to the Office of Management and Budget (OMB) for approval under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). Persons desiring to comment on these information collection requirements should submit their comments to: Office of Regulatory Policy, Office of Management and Budget, 726 Jackson Place, NW., Washington, DC 20503, ATTN: Desk Officer, Coast Guard. Persons submitting comments to OMB are also requested to submit a copy of their comments to the Coast Guard as indicated under "ADDRESSES."

The proposal applies only to organizations requesting to be delegated authority to provide measurement services on behalf of the Coast Guard. Written submissions would be needed to inform the Coast Guard of an applicant's qualifications and capability to provide these services. This proposal would impose no new paperwork burdens on vessel owners requesting vessel measurement.

Environmental Assessment

The Coast Guard has considered the environmental impact of this proposal and concludes that, under the categorical exclusion provision in section 2.B.2.1. of Commandant Instruction M16475.1B, the preparation of an Environmental Assessment, an Environmental Impact Statement, or a Finding of No Significant Impact for this proposal is not required. This proposal is an administrative and procedural regulation which clearly has no environmental impacts.

List of Subjects in 46 CFR Part 69

Measurement standards, Vessels.

For the reasons set forth in the preamble, the Coast Guard proposes to amend 46 CFR Part 69 as follows:

PART 69—MEASUREMENT OF VESSELS

1. The authority citation to Part 69 continues to read as follows:

Authority: 46 U.S.C. 14102, 14103; 49 CFR 1.46; § 69.01-21 issued under 44 U.S.C. 3507, 49 CFR 1.45.

2. Section 69.01-20 is added to read as follows:

§ 69.01-20 Delegation of authority.

(a) Under 46 U.S.C. 14103 and 49 CFR 1.46, the Coast Guard is authorized to delegate to a "qualified person" the authority to measure vessels and to issue appropriate certificates of measurement for U.S. vessels that are required or eligible to be documented as vessels of the United States.

(b) Authority to perform formal tonnage measurement and certification of U.S. commercial, recreational, and public non-combatant vessels may be delegated to an organization that—

- (1) Is a full member of the International Association of Classification Societies (IACS);
- (2) Is incorporated under the laws of the United States, a State of the United States, or the District of Columbia;
- (3) Is capable of providing all formal U.S. tonnage measurement services for vessels domestically and internationally;

(4) Maintains a tonnage measurement staff that has practical experience in measuring U.S. vessels under Coast Guard regulations and under the International Convention on Tonnage Measurement of Ships, 1969; and

(5) Enters into a Memorandum of Agreement, as described in paragraph (d) of this section.

(c) Applications for delegation of authority under this section must be forwarded to the Commandant, U.S. Coast Guard (G-MVI), 2100 Second Street, SW., Washington, DC 20593-0001 and include the following information on the organization:

- (1) Its name and address.
- (2) Its organizational rules and structure.

(3) The location of its offices that are available to provide formal measurement services under Coast Guard regulations or under the International Convention on Tonnage Measurement of Ships, 1969.

(4) The name, qualifications, experience, and job title of each full-time or part-time employee or independent contractor specifically designated by the organization to provide formal measurement services under Coast Guard regulations or under the International Convention on Tonnage Measurement of Ships, 1969; and

(5) Its tonnage measurement training procedures.

(d) If, after reviewing the application, the Coast Guard determines that the organization is qualified to measure and certify U.S. vessels on behalf of the Coast Guard, the organization must enter into a Memorandum of Agreement with the Coast Guard which—

(1) Defines the procedures for administering and implementing the tonnage measurement and certification processes, including the roles and responsibilities of each party;

(2) Outlines the Coast Guard's oversight role;

(3) Prohibits the organization from measuring and certifying the tonnage of any vessel for which an employee or contractor of that organization has been compensated as a tonnage consultant;

(4) Requires the organization to—

(i) Accept all requests to perform delegated services without discrimination and without regard to the vessel's location, unless prohibited from doing so under the laws of the jurisdiction in which the vessel is located or of the United States;

(ii) Physically inspect each vessel before issuing a tonnage certificate;

(iii) Provide the Coast Guard with current schedules of fees and related charges;

(iv) Maintain a tonnage measurement file for each U.S. vessel that the organization measures and permit access to the file by any person authorized by the Commandant;

(v) Permit observer status representation by the Coast Guard at all formal discussions that may take place between the organization and other vessel tonnage measurement organizations pertaining to tonnage measurement of U.S. vessels or to the systems under which U.S. vessels are measured;

(vi) Comply with and apply all laws and regulations relating to tonnage measurement of U.S. vessels within the scope of authority delegated; and

(vii) Comply with all other provisions, if any, of the Memorandum of Agreement.

(e) Upon delegation of authority, the organization is listed in § 69.01-11(a), Measurement sources.

P.C. Lauridsen,

*Captain, U.S. Coast Guard, Acting Chief,
Office of Marine Safety, Security and
Environmental Protection.*

November 25, 1987.

[FR Doc. 87-27816 Filed 12-3-87; 8:45 am]

BILLING CODE 4910-14-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Proposed Rule To Reclassify the Alabama Cavefish (*Speoplatyrhinus poulsoni*), From Threatened to Endangered

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Service proposes to reclassify the Alabama cavefish, *Speoplatyrhinus poulsoni*, from threatened to endangered under the authority of the Endangered Species Act of 1973, as amended. The critical habitat designation would remain unchanged. The Alabama cavefish is known only from Key Cave in Lauderdale County, Alabama. A hydrological survey for a proposed solid waste landfill determined an existing sewage sludge disposal operation is within the recharge area of Key Cave (Aley 1986). The land immediately above and around Key Cave has numerous sinkholes and water collecting depressions and is in agricultural row-crops. The application of pesticides to these crops may impact the fauna in Key Cave. This proposal, if made final, would increase the protection provided by the Endangered

Species Act of 1973, as amended. The Service is requesting comments and data from the public on this proposal.

DATES: Comments from all interested parties must be received by February 2, 1988. Public hearing requests must be received by January 19, 1988.

ADDRESSES: Comments and materials concerning this proposal should be sent to the Field Supervisor, U.S. Fish and Wildlife Service, Jackson Mall Office Center, Suite 316, 300 Woodrow Wilson Avenue, Jackson, MS 39213. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: James H. Stewart at the above address (601/965-4900).

SUPPLEMENTARY INFORMATION:

Background

The Alabama cavefish was described by J. E. Cooper and R. A. Kuehne in 1974. *Speoplatyrhinus* is a monotypic genus known from only Key Cave, Lauderdale County, Alabama. It was first collected in 1967 by Cooper (Cooper and Kuehne 1974). Only nine Alabama cavefish in total are known to have been collected. The population in Key Cave is estimated at fewer than 100 individuals by Cooper (USFWS 1985). The largest number of cavefish ever observed on a single visit to Key Cave was 10 individuals.

The Alabama cavefish lacks externally visible eyes and pigmentation. Like all other members of the cavefish family, it has a jugular vent and a large branchial cavity, probably for oral incubation of eggs. Pelvic fins are absent and the head is elongated and flattened. The typical length is just less than three inches (about 7 centimeters) (Cooper and Kuehne 1974).

The Service initially listed the Alabama cavefish as a threatened species and designated Key Cave as critical habitat on October 11, 1977 (42 FR 45526). Since the initial listing, the Service funded a survey of caves in Lauderdale and Colbert Counties, Alabama, in 1985 and a follow-up survey of three caves in 1986, in an effort to locate other populations of Alabama cavefish. This project studied 120 caves, 27 of which were surveyed in 1985 (Cobb 1985). The remaining caves were not field surveyed because earlier surveys had found southern cavefish or no fauna, or determined that permanent water was not present. Southern cavefish (*Typhlichthys subterraneus*) and Alabama cavefish are not known to co-exist, possibly because of

competition for food and space. In the 1985 survey, three caves were selected for further survey in 1986 because of habitat present or the sighting of a cavefish. The 1986 survey did not capture any cavefish, but its observations further strengthened the probability these are southern cavefish (Cobb 1986). The southern cavefish, *Typhlichthys subterraneus*, occurs to the east and south of Key Cave and probably also to the north (Cobb 1985, 1986).

The type locality of the Alabama cavefish is situated in the Warsaw component of Tusculumbia limestone, which is known to contain caves only in the western portion of Lauderdale County. Geologically, the Key Cave area is not part of a continuous cave-containing limestone area (the western two thirds of Lauderdale County contains the Fort Payne chert formation, of a different geologic age) (Cobb 1985). Key Cave is a relatively large and multi-level cave with over 10,000 feet (3,048 meters) of mapped passage. Water depths may approach 20 feet in late spring (USFWS 1985). The Tennessee Valley Authority (TVA) owns the two entrances and has erected a fence to discourage spelunkers. Most of the surrounding land is privately owned. A hydrological study for a proposed solid waste landfill near Key Cave concluded that the recharge area for this cave included most or all of the land lying above the elevation of Pickwick Lake in eight sections of T3S, R12W (Aley 1986). Most of this area is in agricultural row-crops. A sewage sludge disposal project developed by TVA and operated intermittently by the City of Florence, Alabama is probably within this recharge area.

Summary of Factors Affecting the Species

Section 4(a)(1) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal Lists. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1). These factors and their application to the Alabama cavefish (*Speoplatyrhinus poulsoni*) are as follows:

A. The present or threatened destruction, modification, or curtailment of its habitat or range. Groundwater contamination represents a major threat to the Alabama cavefish. Most of the probable recharge area for key Cave is

in agricultural production (Aley 1986). The topography is marked by sinkholes and water-collecting depressions. The Florence Demonstration Project involves land application of municipal sludge from the City of Florence and is likely to be within the recharge area for Key Cave (Aley 1986). Contaminants from agriculture activities and the sewage sludge application probably enter the Key Cave aquifer since Aley (1986) believes that virtually all the land is drained through the groundwater system.

B. Overutilization for commercial, recreational, scientific or educational purposes. Obligate cave species characteristically live longer and have considerable lower reproductive capacities than related surface species (Poulson 1961). Offers to purchase cavefish has appeared in various publications, and scientific collectors have often taken all the individuals encountered in an area. Reduction of the cavefish population by whatever event could reduce the population below the sustaining level.

C. Disease or predation. Disease in cavefish has not been studied but it is reasonable to assume they are susceptible to disease outbreaks, especially when water quality deteriorates. Predation may be a threat. Raccoons and epigeal fishes are known to prey upon cavefish, as are cave crayfish. Raccoons may venture great distances into a cave preying upon whatever they catch. Key Cave has a relatively abundant population of cave crayfish.

D. The inadequacy of existing regulatory mechanisms. The Alabama cavefish is listed as threatened under authority of the Endangered Species Act of 1973, as amended. Under this designation, permits may be issued for zoological exhibition or educational purposes. The present status of this species does not warrant issuance of permits for such purposes.

E. Other natural or manmade factors affecting its continued existence. Cavefish are very dependent upon the energy source supporting the food supply. In Key Cave, the primary energy source is guano from a maternity colony of the endangered gray bat, *Myotis grisescens*. A decline in this maternity colony would undoubtedly affect the Alabama cavefish. The low reproductive capability and low population are natural limitations to the ability of this species to recover from any adversity.

The Service has carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this

species in determining to propose this reclassification. Based on this evaluation, the preferred action is to reclassify the Alabama cavefish as endangered. This reclassification is appropriate because (1) this species is still known from only one cave after extensive surveys of other caves in the vicinity, (2) the population is very small in this one cave, and (3) the water quality in this cave is probably being degraded by surface activities. These factors and those described earlier place the Alabama cavefish in danger of extinction.

Critical Habitat

This rule does not propose any change in the critical habitat as presently designated.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Endangered Species Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in conservation actions by Federal, State, and private agencies, groups, and individuals. The Endangered Species Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. Such actions were initiated by the Service for this species following its listing. The protection required of Federal agencies and the prohibitions against taking and harm are discussed, in part, below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR Part 402. Section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service. Since the Alabama cavefish is already protected under Section 7 of the act by its listing as threatened, reclassification to endangered will not affect this requirement. For example, Federal involvement with the Alabama

cavefish will probably continue to involve the Environmental Protection Agency in pesticide registration and water contamination.

The Act and implementing regulations found at 50 CFR 17.21 set forth a series of general prohibitions and exceptions that apply to all endangered wildlife. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to take, import or export, ship in interstate commerce in the course of a commercial activity, or sell or offer for sale in interstate or foreign commerce any listed species. It also is illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to agents of the Service and State conservation agencies.

Permits may be issued to carry out otherwise prohibited activities involving endangered wildlife species under certain circumstances. Regulations governing permits are at 50 CFR 17.22 and 17.23, and at 17.32 for threatened species. Such permits are available for scientific purposes, to enhance the propagation or survival of the species, and/or for incidental take in connection with otherwise lawful activities. In some instances, permits may be issued during a specified period of time to relieve undue economic hardship that would be suffered if such relief were not available. A narrower range of permits will be available for the Alabama cavefish as a result of this reclassification.

Public Comments Solicited

The Service intends that any final action resulting from this proposal will be accurate and as effective as possible. Therefore, any comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other party concerning any aspect of this proposal are hereby solicited. Comments particularly are sought concerning:

(1) Biological, commercial trade, or other relevant data concerning any threat (or lack thereof) to this species;

(2) The location of any additional populations of this species and the reasons why any habitat should or should not be determined to be critical habitat as provided by Section 4 of the Act;

(3) Additional information concerning the range and distribution of this species; and

(4) Current or planned activities in the subject area and their possible impacts on this species.

Final promulgation of the regulation on this species will take into consideration the comments and any additional information received by the Service, and such communications may lead to adoption of a final regulation that differs from this proposal.

The Endangered Species Act provides for a public hearing on this proposal, if requested. Requests must be filed within 45 days of the date of the proposal. Such requests must be made in writing and addressed to Endangered Species Field Supervisor (see ADDRESSES section).

National Environmental Policy Act

The Fish and Wildlife Service has determined that an Environmental Assessment, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to Section 4(a) of the Endangered Species Act of 1973, as amended. A notice outlining the Service's reasons for this determination was published in the *Federal Register* on October 25, 1983 (48 FR 49244).

References Cited

- Aley, T. 1986. Hydrogeologic Investigations for a Proposed Landfill near Florence, Alabama. A contract study and report for Waste Contractors, Inc. 20 pp.
- Cobb, R.M. 1985. A Reconnaissance of Caves in Lauderdale and Colbert Counties, Alabama for the Alabama cavefish, *Speoplatyrhinus poulsoni*. A survey and report for the U.S. Fish and Wildlife Service. 26 pp. with field data forms.
- Cobb, R.M. An Attempt to Collect Specimens of Cavefish at Three Cave Sites in Northeast Alabama. A survey and report for the U.S. Fish and Wildlife Service. 8 pp.

Copper, J.E. and R.A. Kuehne. 1974.

Speoplatyrhinus poulsoni: A new Genus and Species of Subterranean Fish from Alabama. *Copeia* (2):486-493.

Poulson, T.L. 1961. Cave Adaptation in Amblyopsid Fishes. Ph. D. dissert., Univ. Mich. Ann Arbor. 185 pp.

U.S. Fish and Wildlife Service. 1985. Revised Recovery Plan for the Alabama cavefish *Speoplatyrhinus poulsoni*. Copper and Kuehne 1974. 64 pp.

Author

The primary author of this proposed rule is James Stewart (see ADDRESSES section).

List of Subjects in 50 CFR Part 17

Endangered and threatened wildlife, Fish, Marine mammals, Plants (agriculture).

Proposed Regulation Promulgation

PART 17—[AMENDED]

Accordingly, it is hereby proposed to amend Part 17, Subchapter B of Chapter I, Title 50 of the Code of Federal Regulations, as set forth below:

1. The authority citation for Part 17 continues to read as follows:

Authority: Pub. L. 93-205, 87 Stat. 884; Pub. L. 94-359, 90 Stat. 911; Pub. L. 95-632, 92 Stat. 3751; Pub. L. 96-159, 93 Stat. 1225; Pub. L. 97-304, 96 Stat. 1411 (16 U.S.C. 1531 *et seq.*); Pub. L. 99-625, 100 Stat. 3500 (1986), unless otherwise noted.

§ 17.11 [Amended]

2. It is proposed to amend § 17.11(h), the list of Endangered and Threatened Wildlife, under FISHERIES, by revising the "Status" column for the entry "Cavefish, Alabama * * *" to read "E" instead of "T", and revising the "When listed" column for the same species accordingly.

Dated: October 22, 1987.

Susan Reece,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 87-27914 Filed 12-3-87; 8:45 am]

BILLING CODE 4310-55-M

Notices

Federal Register

Vol. 52, No. 233

Friday, December 4, 1987

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Department of Agriculture Programs and Activities Excluded From or Subject to Executive Order No. 12372

AGENCY: Office of the Secretary, USDA.

ACTION: Final notice.

SUMMARY: This final notice presents a USDA list of two new programs subject to and ten new programs excluded from coverage of Executive Order No. 12372, "Intergovernmental Review of Federal Programs."

EFFECTIVE DATE: December 4, 1987.

FOR FURTHER INFORMATION CONTACT: Gerald R. Miske, Office of Finance and Management, U.S. Department of Agriculture, Room 1369, South Building, 14th and Independence Avenue, SW., Washington, DC 20250, telephone: 202-382-1553.

SUPPLEMENTARY INFORMATION: The requirements of the Executive Order are detailed at 7 CFR Part 3015, Subpart V. Current lists of programs and activities excluded from and subject to Executive Order No. 12372 are published at 48 FR 29114-29117 (June 24, 1983), as supplemented by 48 FR 54317 (December 1, 1983), 49 FR 22675 (May 31, 1984), 50 FR 1040 (January 9, 1985), 50 FR 14088 (April 10, 1985), 50 FR 24612 (June 12, 1985), 50 FR 47034 (November 14, 1985), and 50 FR 48741 (November 27, 1985). The programs are listed by the Catalog of Federal Domestic Assistance Number assigned to them. The Department published a Notice in the *Federal Register* on June 16, 1987 (52 FR 22831), proposing to exclude ten new programs and include two new programs from the coverage of Executive Order No. 12372. The public comment period ended on July 16, 1987.

Discussion of Comments: The Department received five comments during the comment period. Four of the

comments endorsed the list without objection. One letter contained comments on two programs from two regional entities. One entity voluntarily withdrew its objections. The other entity objected to the exclusion of the Small Business Innovative Research program because the entity wanted to be kept informed of all such programs in their State.

Although USDA understands this concern, the Department has determined that this program is appropriately excluded because it is outside the scope of Executive Order 12372 as it does not directly affect State and local governments.

Accordingly, the list of programs and activities excluded is supplemented by adding the following ten programs:

Agricultural Stabilization and Conservation Service

10.069 Conservation Reserve Program (CRP). The CRP is authorized by title XII of the Food Security Act of 1985 and is administered by ASCS. Under the CRP, the Secretary of Agriculture is authorized to enter into long-term contracts with owners and operators of highly erodible cropland to assist them in conserving and improving the Nation's soil and water resources. By entering into a contract, based on an accepted bid process, the owner or operator agrees to implement a conservation plan approved by the local conservation district for converting highly erodible cropland normally devoted to the production of an agricultural commodity to a less intensive use. The Secretary will provide technical assistance, share some of the costs of establishing the conservation practices required by the conservation plan, and make an annual land rental payment to compensate the owner or operator for taking the cropland out of production.

Cooperative State Research Service

10.120 Food and Agricultural Sciences National Needs Graduate Fellowship Grants Program (FASNNGFGP). The CSRS-FASNNGFGP provides grants to colleges and universities to encourage outstanding students to pursue graduate degrees in areas of the food and agricultural sciences for which there are national needs for the development of scientific expertise.

10.211 Higher Education Strengthening Grants (HESG). CSRS-HESG provides grants to strengthen institutional capacities to respond to State, regional, national, or international educational needs in the food and agricultural sciences.

10.212 Small Business Innovative Research (SBIR). CSRS-SBIR provides grants for research to stimulate technological innovation in the private sector, strengthen the role of small business in meeting Federal research and development needs, increase private sector commercialization of innovations derived from USDA supported research and development efforts, and foster and encourage minority and disadvantaged participation in technological innovation.

10.213 Competitive Research Grants Program for Forest and Rangeland Renewable Resources (CRGPFRRR). CSRS-CRGPFRRR provides competitive research grants to further research activities related to the protection, management, and utilization of forest and rangeland renewable resources.

Foreign Agricultural Service

10.601 Targeted Export Assistance Program (TEA). The FAS-TEA program is carried out pursuant to section 1124 of the Food Security Act of 1985. Under TEA, the Secretary of Agriculture is required to use \$110 million in Commodity Credit Corporation (CCC) funds or commodities in each of the fiscal years 1986 to 1988 to counter or offset the adverse effect on the export of a U.S. Agricultural commodity, or the product thereof, of a subsidy, an import quota, or other unfair foreign trade practice. In fiscal years 1989 and 1990, the minimum amount of funds or commodities required to be used will increase to not less than \$325 million. Targeted export assistance is being provided through program agreements with nonprofit U.S. agricultural trade associations or with private U.S. firms. Program agreements provide for partial reimbursement of eligible promotional expenses identified in FAS-approved activity plans which describe the activities and budgets to be conducted in foreign markets.

Office of Advocacy and Enterprise

10.140 Minority Research and Teaching (MRT). The OAE-MRT

program makes grants in full or in partial support of special projects related to agriculture that are undertaken by educational institutions, such as the 1890 Land Grant Institutions for purposes of enhancing curriculum, developing faculty, and recruiting and retaining students in agricultural programs.

Office of International Cooperation and Development

10.960 Technical Agricultural Assistance (TAA). The OICD-TAA program, pursuant to the terms of reimbursable agreements with the Agency for International Development, funds cooperative agreements, grants, and cost reimbursable agreements to increase the capabilities of U.S. educational institutions and non-profit agencies in agricultural research, teaching, and extension and to identify and apply the most appropriate solutions to international agricultural problems.

10.961 Technical Agricultural Research/Collaborative (TAR/C). The OICD-TAR/C program funds cooperative agreements, grants, and cost reimbursable agreements to carry out the administration and coordination of assigned Departmental programs in international research and scientific and technical cooperation with other government agencies, land grant universities, international organizations, international agricultural research centers, and other institutions.

10.962 International Training/Foreign (IT/F). The OICD-IT/F program, pursuant to the terms of reimbursable agreements with the Agency for International Development (AID), funds cooperative agreements, grants, and cost reimbursable agreements to provide training opportunities in food, agricultural and related research, teaching, and extension to representatives of AID designated countries.

Additionally, the list of programs and activities included is supplemented by adding the following two programs:

Animal and Plant Health Inspection Service

10.028 Animal Damage Control (ADC). The APHIS-ADC program's primary purpose is to minimize or prevent (1) damage to domestic livestock, agriculture, horticulture, forestry, and rangelands from predator and other animals injurious to agriculture, and (2) to protect stock and other domestic animals through the suppression of rabies and tularemia in predatory or other wild animals.

To accomplish these objectives, APHIS-ADC conducts research to investigate the nature and scope of vertebrate behavior patterns for use in development of new or improved methods to control predator and other animals injurious to agriculture. The new or improved methods developed are applied by APHIS in cooperation with State and local governments, and other Federal agencies to control predator and other animals injurious to agriculture. Techniques such as trapping and removal, mechanical scaring, chemical repelling, and fencing are employed.

Farmers Home Administration

10.434 Nonprofit National Corporation Loan and Grant (NNCLG). The FmHA-NNCLG program provides guaranteed loans and grants to nonprofit corporations that will in turn provide financial and technical assistance to rural businesses to improve business, industry, and employment opportunities in rural areas.

Dated: November 30, 1987.

Ernest H. Matthias,
Special Assistant to the Assistant Secretary for Administration.

[FR Doc. 87-27906 Filed 12-3-87; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket No. 39-87]

Foreign-Trade Zone 82, Mobile, AL; Application for Subzone, Degussa Methionine Plant, Mobile County

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the City of Mobile, Alabama, grantee of FTZ 82, requesting special-purpose subzone status for the methionine manufacturing facility of Degussa Corporation, a subsidiary of Degussa AG of West Germany, located in Mobile County, Alabama, adjacent to the Mobile Customs port of entry. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on November 23, 1987.

The plant (193 acres) is located on Highway 24, south of Hamilton Blvd., in Mobile County, some 2 miles southeast of Theodore, and 10 miles south of Mobile. The facility employs 500 persons and is used to produce methionine, aerosil, cyanuric chloride, hydrocyanic acid, and ammonium sulfate, but zone

procedures are being requested at this time only for the production of methionine, and amino acid used as an agricultural feed supplement. The primary ingredient is methylmercaptopropionaldehyde (MMP) which is sourced abroad.

Zone procedures would exempt Degussa from Customs duty payments on its reexports. On its domestic sales, the company would be able to pay duties at the rate available to importers of methionine. The duty rate for methionine is 4.4 percent whereas the rate for MMP is 6.0 percent. The applicant indicates that the zone savings would help improve the company's international competitiveness.

In accordance with the Board's regulations, an examiners committee has been appointed to investigate the application and report to the Board. The committee consists of: Dennis Puccinelli (Chairman), Foreign-Trade Zones Staff, U.S. Department of Commerce, Washington, DC 20230; David Willette, District Director, U.S. Customs Service, South Central Region, P.O. Box 2748, Mobile, AL 36652; and Colonel C. Hilton Dunn, Jr., District Engineer, U.S. Army Engineer District Mobile, P.O. Box 2288, Mobile, AL 36628.

Comments concerning the proposed subzone are invited in writing from interested parties. They should be addressed to the Board's Executive Secretary at the address below and postmarked on or before January 22, 1988.

A copy of the application is available for public inspection at each of the following locations:

District Director, U.S. Customs Service,
250 N. Water Street, Mobile, AL 36652
Office of the Executive Secretary,
Foreign-Trade Zones Board, U.S.
Department of Commerce, Room 1529,
14th and Pennsylvania NW.,
Washington, DC 20230.

Dated: November 30, 1987.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 87-27886 Filed 12-3-87; 8:45 am]

BILLING CODE 3510-DS-M

[Docket No. 31-87]

Foreign-Trade Zone 72, Indianapolis, IN; Application for Subzone at Subaru-Isuzu Auto/Truck Plant in Tippecanoe County, IN; Correction

On November 20, 1987, notice was given concerning a proposal for a special-purpose subzone for the automobile/light truck manufacturing plant of Subaru-Isuzu Automotive, Inc.,

in Tippecanoe County, Indiana (52 FR 44620, 11/20/87).

In referring to the member of the examiners committee designated from the U.S. Customs Service, the notice is amended to show a new committee member from Customs. The new member is: John F. Nelson, District Director, U.S. Customs Service, North Central Region, 6th Floor, Plaza Nine Building, 55 Erieview Plaza, Cleveland, Ohio 44114.

Dated: December 1, 1987.

Dennis Puccinelli,

Acting Executive Secretary.

[FR Doc. 87-27885 Filed 12-3-87; 8:45 am]

BILLING CODE 3510-DS-M

[Order No. 367]

Resolution and Order Approving Application of County of Onondaga, NY, for Subzone for Chrysler Corp.

Proceedings of the Foreign-Trade Zones Board, Washington, DC.

Resolution and Order

Pursuant to the authority granted in the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), the Foreign-Trade Zones Board has adopted the following Resolution and Order:

The Board, having considered the matter, hereby orders:

After consideration of the application of the County of Onondaga, New York, grantee of Foreign-Trade Zone 90, filed with the Foreign-Trade Zones Board (the Board) on May 2, 1986, requesting special-purpose subzone status for the transmission/transaxle manufacturing plant of Chrysler Corporation in Onondaga County, New York, adjacent to the Syracuse Customs port of entry, the Board, finding that the requirements of the Foreign-Trade Zones Act, as amended, and the Board's regulations are satisfied, and that the proposal is in the public interest, approves the application.

The Secretary of Commerce, as Chairman and Executive Officer of the Board, is hereby authorized to issue a grant of authority and appropriate Board Order.

Grant of Authority To Establish a Foreign-Trade Subzone in Onondaga County, NY

Whereas, by an Act of Congress approved June 18, 1934, an Act "To provide for the establishment, operation, and maintenance of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes", as amended (19 U.S.C. 81a-81u) (the Act), the Foreign-Trade Zones Board (the Board) is authorized and empowered to

grant to corporations the privilege of establishing, operating, and maintaining foreign-trade zones in or adjacent to ports of entry under the jurisdiction of the United States;

Whereas, the Board's regulations (15 CFR 400.304) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved, and where a significant public benefit will result;

Whereas, the County of Onondaga, New York, grantee of Foreign-Trade Zone No. 90, has made application (filed May 2, 1986, Docket 15-86, 51 FR 17506) in due and proper form to the Board for authority to establish a special-purpose subzone at the automobile transmission plant of Chrysler Corporation in Onondaga County, New York, adjacent to the Syracuse Customs port of entry;

Whereas, notice of said application has been given and published, and full opportunity has been afforded all interested parties to be heard; and

Whereas, the Board has found that the requirements of the Act and the Board's regulations are satisfied;

Now, therefore, in accordance with the application filed May 2, 1986, the Board hereby authorizes the establishment of a subzone at Chrysler's plant in Onondaga County, designated on the records of the Board as Foreign-Trade Subzone No. 90B at the location mentioned above and more particularly described on the maps and drawings accompanying the application, said grant of authority being subject to the provisions and restrictions of the Act and the Regulations issued thereunder, to the same extent as though the same were fully set forth herein, and also to the following express conditions and limitations:

Activation of the subzone shall be commenced within a reasonable time from the date of issuance of the grant, and prior thereto, any necessary permits shall be obtained from Federal, State, and municipal authorities.

Officers and employees of the United States shall have free and unrestricted access to and throughout the foreign-trade subzone in the performance of their official duties.

The grant shall not be construed to relieve responsible parties from liability for injury or damage to the person or property of others occasioned by the construction, operation, or maintenance of said subzone, and in no event shall the United States be liable therefor.

The grant is further subject to settlement locally by the District Director of Customs and the District Army Engineer with the grantee regarding compliance with their

respective requirements for the protection of the revenue of the United States and the installation of suitable facilities.

In witness whereof, the Foreign-Trade Zones Board has caused its name to be signed and its seal to be affixed hereto by its Chairman and Executive Officer or his delegate at Washington, DC this 24th day of November, 1987, pursuant to Order of the Board.

Foreign-Trade Zones Board.

Gilbert B. Kaplan,

Acting Assistant Secretary of Commerce for Import Administration, Chairman, Committee of Alternates.

Attest:

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 87-27887 Filed 12-3-87; 8:45 am]

BILLING CODE 3510-DS-M

National Oceanic and Atmospheric Administration

Coastal Zone Management; Federal Consistency Appeal by Auld Brass Hunting Club from an Objection by the South Carolina Coastal Council

AGENCY: National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of appeal.

On September 14, 1987, the Department of Commerce received a letter from Auld Brass Hunting Club (Appellant) filing a Notice of Appeal under section 307(c)(3)(A) of the Coastal Zone Management Act of 1972, 16 U.S.C. 1456(c)(3)(A), and the Department of Commerce's implementing regulations, 15 CFR Part 930, Subpart H (1987). The appeal is taken from an objection by the South Carolina Coastal Council to Appellant's after-the-fact consistency certification for U.S. Army Corps of Engineers Permit Application No. 87-3S-184-C, under section 10 of the River and Harbor Act of 1899 and section 404 of the Federal Water Pollution Control Act, for enlargement of a drainage ditch and placement of the material excavated in wetlands along the Combahee River in Beaufort County, South Carolina. If Appellant perfects the appeal by stating the specific grounds for it and filing the supporting statement, data and information required by the Department's implementing regulations, public comments will be solicited by a notice in the Federal Register and a local newspaper.

FOR ADDITIONAL INFORMATION CONTACT: Cynthia Mackey, Office of the Assistant General Counsel for Ocean Services,

National Oceanic and Atmospheric Administration, U.S. Department of Commerce, 1825 Connecticut Avenue, NW., Suite 603, Washington, DC 20235, (202) 673-5200.

(Federal Domestic Assistance Catalog No. 11.419 Coastal Zone Management Program Assistance)

Date: November 27, 1987.

Daniel W. McGovern,
General Counsel.

[FR Doc. 87-27813 Filed 12-3-87; 8:45 am]

BILLING CODE 3510-08-M

Coastal Zone Management; Federal Consistency Appeal by Westvaco Development Corp. From an Objection by the South Carolina Coastal Council

AGENCY: National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of appeal.

On October 22, 1987, the Department of Commerce (Department) received a letter from J. Reed Atkinson, on behalf of a Westvaco Development Corporation (Appellant), filing a Notice of Appeal under section 307(c)(3)(A) of the Coastal Zone Management Act of 1972, 16 U.S.C. 1456(c)(3)(A), and the Department's implementation regulations, 15 CFR Part 930, Subpart H (1987). The appeal is taken from an objection by the South Carolina Coastal Council (State) to the Appellant's consistency certification for U.S. Army Corps of Engineers Permit Application No. SAC-26-87-548B, under section 404 of the Clean Water Act, 33 U.S.C. 1344, for placing fill material into a wetland for residential development in Berkeley County, South Carolina.

If the Appellant perfects the appeal by filing the supporting data and information required by the Department's implementing regulations, public comments will be solicited by a notice in the *Federal Register* and a local newspaper.

FOR ADDITIONAL INFORMATION CONTACT:

Cynthia L. Mackey, Attorney-Adviser, Office of the Assistant General Counsel for Ocean Services, National Oceanic and Atmospheric Administration, U.S. Department of Commerce, 1825 Connecticut Avenue NW., Suite 603, Washington, DC 20235, (202) 673-5200.

(Federal Domestic Assistance Catalog No. 11.419 Coastal Zone Management Program Assistance)

Date: November 27, 1987.

Daniel W. McGovern,
General Counsel.

[FR Doc. 87-27819 Filed 12-3-87; 8:45 am]

BILLING CODE 3510-08-M

Permits; Foreign Fishing

This document publishes for public review a summary of applications received by the Secretary of State requesting permits for foreign vessels to fish in the exclusive economic zone under the Magnuson Fishery Conservation and Management Act (Magnuson Act, 16 U.S.C. 1801 *et seq.*)

Send comments on applications to: Fees and Permits Branch (F/TS21), National Marine Fisheries Service, Department of Commerce, Washington, DC 20235

or, send comments to the Fishery Management Council(s) which review the application(s), as specified below:

Douglas G. Marshall, Executive Director, New England Fishery Management Council, 5 Broadway (Route 1), Saugus, MA 01906, 617/231-0422

John C. Bryson, Executive Director, Mid-Atlantic Fishery Management Council, Federal Building Room 2115, 320 South New Street, Dover, DE 19901, 302/674-2331

Robert K. Mahood, Executive Director, South Atlantic Fishery Management Council, Southpark Building, Suite 306, 1 Southpark Circle, Charleston, SC 29407, 803/571-4366

Omar Munoz-Roure, Executive Director, Caribbean Fishery Management Council, Banco De Ponce Building, Suite 108, Hato Rey, PR 00918, 809/753-4926

Wayne E. Swingle, Executive Director, Gulf of Mexico Fishery Management Council, Lincoln Center, Suite 881, 5401 West Kennedy Blvd., Tampa, FL 33609, 813/228-2815

Lawrence D. Six, Executive Director, Pacific Fishery Management Council, Metro Building, Suite 420, 2000 SW. First Avenue, Portland, OR 97201, 503/221-6352

Jim H. Branson, Executive Director, North Pacific Fishery Management Council, P.O. Box 103136, Anchorage, AK 99510, 907/274-4563

Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council, 1164 Bishop Street, Room 1405, Honolulu, HI 96813, 808/523-1368

For further information contact John D. Kelly or Shirley Whitted (Fees and Permits Branch, 202-673-5319).

The Magnuson Act requires the Secretary of State to publish a notice of receipt of all applications for such permits summarizing the contents of the applications in the *Federal Register*. The National Marine Fisheries Service, under the authority granted in a memorandum of understanding with the Department of State effective November

29, 1983, issues the notice on behalf of the Secretary of State.

Individual vessel applications for fishing in 1988 have been received from the Governments shown below.

Dated: December 2, 1987.

Carmen J. Blondin,

Special Associate for Trade, National Marine Fisheries Service, NOAA.

Fishery codes and designation of Regional Fishery Management Councils which review applications for individual fisheries are as follows:

Code Fishery and Regional Fishery Management Councils

ABS Atlantic Billfishes and Sharks

New England, Mid Atlantic, South Atlantic,

Gulf of Mexico, Caribbean

BSA Bering Sea and Aleutian Islands

Groundfish

North Pacific

GOA Gulf of Alaska

North Pacific

NWA Northwest Atlantic Ocean

New England, Mid-Atlantic

SNA Snails (Bering Sea)

North Pacific

WOC Pacific Groundfish (Washington, Oregon and California)

Pacific

PBS Pacific Billfishes and Sharks

Western Pacific

Activity codes which specify categories of fishing operations applied for are as follows:

Activity Code and Fishing Operations

1—Catching, processing and other support

2—Processing and other support only

3—Other support only

*—Vessel(s) in support of U.S. vessels Joint Venture)

**—Cargo transport vessels with fish finding equipment on board will receive an activity code 2 to enable them to perform both scouting as well as support activities.

Joint Venture

The Governments of the People's Republic of China (China), Iceland, Japan, the Republic of Korea (Korea), the Polish People's Republic (Poland), and the Union of the Soviet Socialist Republics (U.S.S.R.), have submitted permit applications to engage in joint venture activities during 1988. Foreign vessels will receive transshipments of U.S. harvested fish and appropriate by-catch species. The fisheries for which they have applied are BSA, GOA, NWA, and WOC. Foreign vessels will receive transshipments of U.S. harvested fish and appropriate by-catch species. A list of the vessels will be published at a later date. The following tables summarize their requests:

SPECIES
[In metric tons]

Country	Pollock	Pacific cod	Atka mackerel	Yellowfin sole	Other flounders	Misc
Bering Sea and Aleutian Islands Fisheries:						
China ¹	50,000	5,000	3,000	20,000	3,000	0
Iceland ²	0	30,000	0	0	0	0
Japan ³	812,500	(*)	(*)	(*)	(*)	(*)
Korea ⁵	471,260	26,684	32,286	81,906	8,968	6,370
Poland ⁶	45,000	0	0	0	0	0
U.S.S.R. ⁷	18,000	60,000	15,000	90,000	45,000
Gulf of Alaska:						
China ¹	5,000	1,000	0	0	0	0
Iceland ²	0	10,000	0	0	0	0
Korea ⁵	18,533	1,632	741	0	592	1,028

¹ Chinese partners are: Alaska World Trade Corp., Anchorage, AK; China Pacific Ventures, Inc., Seattle, WA.

² Kris Poulsen & Associates, Seattle, WA.

³ Japanese partners in Seattle, WA: Northern Deep Sea Fisheries, Inc.; Profish International, Inc.; Westward Trawlers, Inc.; Peter Pan Seafoods, Inc.; Alaska Pacific Ltd.; Golden Age Fisheries; and Trawl Resources, Inc. Partners in other locations: Kodiak & Western Trawlers Group, Kodiak, AK; Alyeska Ocean, Inc., Anacortes, WA; and Alaska Contact, Ltd., Anchorage, AK.

⁴ Other Groundfish total—67,500.

⁵ Korean partners in Seattle, WA: Joint Venture Fisheries, Ltd.; Alaska Surimi Products, Inc.; Dona JV Fisheries Co.; Arctic Venture Fisheries, Inc.; Profish Alaska, Inc.; and Cal-Alaska Fisheries, Inc. Partners in other locations: Alaska Joint Venture Fisheries, Anchorage, AK; Alaska Pacific Fisheries, Ltd.; and Daerim America, Inc., Ft. Lee, N.J.

⁶ Polish partners in Seattle, WA: Profish International, Inc. and Alaska Pacific International, Ltd.; and in Coos Bay, OR, Quest Export Trading Co.

⁷ U.S.S.R.: Marine Resources Co. International, Seattle, WA.

THE WASHINGTON, OREGON AND CALIFORNIA TRAWL FISHERIES (WOC) PACIFIC HAKE REQUEST

Country	Pacific Whiting	Other Rockfish	Other Groundfish
Korea.....	5,300	100	⁸ 550
Poland.....	51,000	0	0

⁸ Partner undetermined.

NORTHWEST ATLANTIC OCEAN FISHERIES

Country	Illex	Loligo	Mackerel
Japan ⁹	3,000	3,000	0
Poland ¹⁰ (amendment).....	3,800	0

⁹ Japanese partners: Lund's Fisheries, Inc., Cape May, NJ; Pt. Judith Fisherman's Association, Inc., Narragansett, RI.

¹⁰ Polish partner: Scan Ocean, Inc., Gloucester, MA.

[FR Doc. 87-28029 Filed 12-3-87; 8:45 am]

BILLING CODE 3510-22-M

COPYRIGHT ROYALTY TRIBUNAL

[Docket No. 88-1-86JD]

1986 Jukebox Royalty Distribution Proceeding

AGENCY: Copyright Royalty Tribunal.

ACTION: Notice of controversy; notice of commencement of proceedings.

SUMMARY: Notice is given that a controversy exists regarding the

distribution of the copyright royalties from the 1986 jukebox royalty fund. Accordingly, the Tribunal commences the 1986 jukebox distribution proceeding.

DATE: The effective date of the controversy is December 7, 1987.

FOR FURTHER INFORMATION CONTACT: Robert Cassler, General Counsel; Copyright Royalty Tribunal; 1111 20th Street, NW., Suite 450; Washington, DC 20036 (202) 653-5175.

SUPPLEMENTARY INFORMATION: Section 301.72(b) of the Tribunal's rules requires that after October 1 of each year, the Tribunal shall ascertain whether a controversy exists with regard to the distribution of jukebox royalties to the copyright owner-claimants and to publish notice of its findings in the *Federal Register*. The Tribunal has been informed that the American Society of Composers, Authors and Publishers, Broadcast Music, Inc. and SESAC, Inc., collectively, as a settled group of claimants, claim 100% of the 1986 jukebox royalty fund, and that Asociacion de Compositores y Editores de Musica Latinoamericana claims 8% of the jukebox royalty fund. Accordingly, the Tribunal has determined that a controversy exists, and notice is hereby given that the 1986 jukebox royalty distribution proceeding is commenced, effective December 7, 1987. The structure of the 1986 proceeding will be

announced in an order to the claimants at a later date.

J.C. Argetsinger,
Chairman.

November 30, 1986.

[FR Doc. 87-27910 Filed 12-3-87; 8:45 am]

BILLING CODE 1416-09-M

DEPARTMENT OF DEFENSE

Office of the Secretary

Public Information Collection Requirement Submitted to OMB for Review

The Department of Defense has submitted to OMB for review/approval the following existing collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Each entry contains the following information: (1) Type of Submission; (2) Title of Information Collection and Form Number if applicable; (3) Abstract statement of the need for and the uses to be made of the information collected; (4) Type of Respondent; (5) An estimate of the number of responses; (6) An estimate of the total number of hours needed to provide the information; (7) To whom comments regarding the information collection are to be forwarded; and (8) The point of contact from whom a copy of the information proposal may be obtained.

Extension of Expiration Date**Annual Report on Uniform Commutation Fund**

Some institutions of higher education which host ROTC units elect to receive commutation instead of uniforms for their ROTC programs. The institutions purchase the uniforms for the ROTC students, and are reimbursed by the Services for uniforms and associated custodial costs. The annual report on the fund is an accounting of monies spent and a computation of excess funds for refund to the sponsoring Services.

Participating Institutions of Higher Education: 135 respondents; 155 burden hours.

OMB Desk Officer: Mr. Edward Springer.

Written comments and recommendations on the proposed information collection should be sent to Mr. Edward Springer at Office of Management and Budget, Desk Officer, Room 3235, New Executive Office, Washington, DC 20503.

DOD Clearance Officer: Mrs. Pearl Rascoe-Harrison.

A copy of the information collection proposal may be obtained from Mrs. Pearl Rascoe-Harrison at WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, Virginia 22202-4302, telephone 202/746-0933.

Linda Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

December 1, 1987.

[FR Doc. 87-27854 Filed 12-3-87; 8:45 am]

BILLING CODE 3810-01-M

Renewal of the DoD-University Forum

SUMMARY: Under the provisions of Pub. L. 92-453, Federal Advisory Committee Act, notice is hereby given that the DoD-University Forum has been determined to be in the public interest and has been renewed.

The DoD-University Forum is constituted to provide advice and guidance to the Department of Defense on issues affecting the relationship between DoD and the university community. The Forum plays a unique and invaluable role in such matters as, ensuring the availability of technical manpower required to support DoD technology needs, and the development of policies which foster the involvement of research universities in the generation of the knowledge based required to

maintain technological superiority over potential adversaries.

Patricia H. Means,

OSD Federal Register Liaison Officer, Department of Defense.

November 30, 1987.

[FR Doc. 87-27855 Filed 12-3-87; 8:45 am]

BILLING CODE 3810-01-M

Department of the Navy**Chief of Naval Operations, Executive Panel Advisory Committee; Closed Meeting**

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. app.), notice is hereby given that the Chief of Naval Operations (CNO) Executive Panel Advisory Committee Mine Warfare Capabilities Task Force will meet January 13-14, 1988 from 9 a.m. to 5 p.m. each day, at 4401 Ford Avenue, Alexandria, Virginia. All sessions will be closed to the public.

The purpose of this meeting is to review current and projected U.S. and Allied Mine Warfare capabilities and potential U.S. vulnerabilities in the broad context of maritime operations and related intelligence. These matters constitute classified information that is specifically authorized by Executive order to be kept secret in the interest of national defense and is, in fact, properly classified pursuant to such Executive order. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 552b(c)(1) of title 5, United States Code.

For further information concerning this meeting, contact AnnLynn Cline, Special Assistant to the CNO Executive Panel Advisory Committee, 4401 Ford Avenue, Room 601, Alexandria, Virginia 22302-0268. Phone (703) 756-1205.

Date: November 30, 1987.

Jane M. Virga,

Lieutenant, JAGC, U.S. Naval Reserve, Federal Register Liaison Officer.

[FR Doc. 87-27821 Filed 12-3-87; 8:45 am]

BILLING CODE 3810-AE-M

Chief of Naval Operations, Executive Panel Advisory Committee; Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. app.), notice is hereby given that the Chief of Naval Operations (CNO) Executive Panel Advisory Committee Mine Warfare Capabilities Task Force will meet January 28-29, 1988 from 9

a.m. to 5 p.m. each day, at Panama City, Florida. All sessions will be closed to the public.

The purpose of this meeting is to review current and projected U.S. and Allied Mine Warfare capabilities and potential U.S. vulnerabilities in the broad context of maritime operations and related intelligence. These matters constitute classified information that is specifically authorized by Executive order to be kept secret in the interest of national defense and is, in fact, properly classified pursuant to such Executive order. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 552b(c)(1) of title 5, United States Code.

For further information concerning this meeting, contact AnnLynn Cline, Special Assistant to the CNO Executive Panel Advisory Committee, 4401 Ford Avenue, Room 601, Alexandria, Virginia 22302-0268. Phone (703) 756-1205.

Date: November 30, 1987.

Jane M. Virga,

Lieutenant, JAGC, U.S. Naval Reserve, Federal Register Liaison Officer.

[FR Doc. 87-27820 Filed 12-3-87; 8:45 am]

BILLING CODE 3810-AE-M

Chief of Naval Operations, Executive Panel Advisory Committee; Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. app.), notice is hereby given that the Chief of Naval Operations (CNO) Executive Panel Advisory Committee Training Organization and Management Task Force will meet February 11-12, 1988 from 9 a.m. to 5 p.m. each day, at 4401 Ford Avenue, Alexandria, Virginia. All sessions will be closed to the public.

The purpose of this meeting will include an examination of Navy training to assess how best to organize and manage training to accommodate future requirements, and related intelligence. These matters constitute classified information that is specifically authorized by Executive order to be kept secret in the interest of national defense and is, in fact, properly classified pursuant to such Executive order. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 552b(c)(1) of title 5, United States Code.

For further information concerning this meeting, contact Ann Lynn Cline, Special Assistant to the CNO Executive Panel Advisory Committee, 4401 Ford Avenue, Room 601, Alexandria, Virginia 22302-0268. Phone (703) 756-1205.

Date: November 30, 1987.

Jane M. Virga,

Lieutenant, JAGC, U.S. Naval Reserve,
Federal Register Liaison Officer.

[FR Doc. 87-27823 Filed 12-3-87; 8:45 am]

BILLING CODE 3810-AE-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP87-492-000]

Algonquin Gas Transmission Co.; Intent To Prepare an Environmental Assessment for Algonquin's Marathon Pipeline Project and Request for Comments on Environmental Issues

November 30, 1987.

Proposed Action

Notice is hereby given that the staff of the Federal Energy Regulatory Commission (FERC) will prepare an environmental assessment (EA) on the facilities proposed in the above-referenced docket. Algonquin Gas Transmission Company (Algonquin) is seeking a certificate of public convenience and necessity under section 7 of the Natural Gas Act to construct 8 miles of 12-inch-diameter pipeline in Norfolk and Middlesex Counties, Massachusetts. This pipeline would cross the towns of Medway, Holliston, and Hopkinton adjacent to a Boston Edison Company electric transmission right-of-way for about 6.6 miles of its length north of Milford Street. Maps A-1, A-2, and A-3 show the location of the proposed pipeline facilities.¹ The remainder of the pipeline, 1.4 miles, would not follow an existing utility corridor. Algonquin would construct a new meter station at the north end of the pipeline on property owned by Commonwealth Gas Company (Commonwealth) in the vicinity of Commonwealth's nonjurisdictional liquefied natural gas (LNG) facility in Hopkinton. Commonwealth would construct approximately 1,600 feet of 6- and 12-inch-diameter non-jurisdictional pipeline and regulating facilities on its property in order to interconnect Algonquin's

facilities with Commonwealth's distribution system near the LNG facility. Algonquin also proposes to replace 0.4 mile of existing 3-inch-diameter pipeline with 10-inch-diameter pipeline in the town of Medway and to modify other existing meter stations on its system.

Algonquin would use the 8-mile pipeline to provide firm transportation service of up to 40,000 MMBtu per day of gas for Commonwealth. This service would have a primary term of 20 years and is proposed to commence on November 1, 1988. Commonwealth has indicated that this pipeline would allow it to transfer gas within parts of its distribution system that are currently served solely by either Algonquin or Tennessee Gas Pipeline Company. The new facilities would also make it possible for Commonwealth to obtain for its firm customers the benefits of increased competition between its two interstate pipeline suppliers and enhance Commonwealth's overall flexibility in managing its gas supply. Algonquin's proposed replacement of 0.4 mile of pipeline would allow it to increase deliveries to Commonwealth at Milford, Massachusetts from 2,333 to 3,933 MMBtu per day of gas.

The proposed 8 miles of 12-inch-diameter pipeline would require a 50-foot-wide construction right-of-way with 30 feet to be maintained as permanent right-of-way. This proposed pipeline begins on the north side of Milford Street following the existing powerline and would continue north across Washington Street, Gorwin Drive, Marshall Street, Hanlon Road, South Mill Street, Chestnut Street, Ash Street, and East Main Street before ending on Commonwealth's property off Wilson Street. Approximately 50 acres would be disturbed by construction activities and about 29 acres would be retained as permanent right-of-way.

The 10-inch-diameter replacement pipeline would be located within Algonquin's existing 30-foot-wide right-of-way. However, construction of this pipeline would require the temporary use of an additional 20-foot-wide easement outside of and adjacent to the existing pipeline right-of-way. This pipeline easement would parallel an unnamed, unimproved road and cross only one road, Granite Street. Construction of this pipeline would disturb approximately 2.4 acres and no additional permanent right-of-way is proposed.

Environmental Issues

The EA will address the environmental concerns that have been identified by the staff and by individuals

in their letters to the FERC and at a public meeting held by the Massachusetts Energy Facilities Siting Council. The following issues have been identified to date:

Water Resources

- Impact on streams.
- Effect on the town of Holliston's water wells and private wells.

Pipeline Safety

- Safety considerations.
- Blasting.
- Pipeline abandonment and removal procedures.

Cultural Resources—Effect on historic properties.

Land Use—Effect on the Charles Bird Property, a hazardous waste site, and Town of Holliston Landfill site.

Vegetation

- Impact on wetlands.
- Removal and disposal of trees.

Land Use

- Eminent domain.
- Impact on homes and future development.
- Impact on septic systems.
- Use of Boston Edison Company electric transmission right-of-way.

Aesthetics—Effect of appearance of right-of-way.

Soils—Restoration of the right-of-way including removal of surface rock.

Alternatives, route modifications, and specific mitigating measures will also be considered in the staff's analysis. The EA will also address the environmental impact resulting from the construction and operation of Commonwealth's nonjurisdictional facilities that are related to Algonquin's proposal.

The EA will be based on the staff's independent analysis of the proposal and, together with the comments received, will comprise part of the record to be considered by the Commission in this proceeding. The EA will be sent to all parties in this proceeding, to those providing comments in response to this notice, to Federal and state agencies, to interested members of the public, and to those individuals that provide a mailing address at the Massachusetts Energy Facilities Siting Council public meeting for this project.

The EA may be offered as evidentiary material if an evidentiary hearing is held in this proceeding. In the event that an evidentiary hearing is held, anyone not previously a party to this proceeding and wishing to present evidence on environmental or other matters must first file with the Commission a motion to intervene, pursuant to Rule 214 of the Commission's Rules of Practice and Procedure. (18 CFR 385.214).

¹ Maps A-1, A-2, and A-3 are not printed in the Federal Register, but are available from the FERC's Division of Program Management, Public Reference Section, telephone (202) 357-8118.

Comment Procedures

Comments from Federal, state, and local agencies and the public are requested to help identify significant issues or concerns related to the proposed action, to determine the scope of the issues that need to be analyzed, and to identify and eliminate from detailed study the issues which are not significant. All comments on specific environmental issues should contain supporting documentation or rationale. Written comments should be submitted on or before December 31, 1987, reference Docket No. CP87-492-000, and be addressed to the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. A copy of the comments should also be sent to Mr. Kenneth Frye, Project Manager, Federal Energy Regulatory Commission, Office of Pipeline and Producer Regulation, Environmental Evaluation Branch, Room 7112C, 825 North Capitol Street, NE., Washington, DC 20426.

Maps showing the location of the proposed pipeline facilities have been provided to those on the distribution list. Algonquin has also made copies of its application available for public inspection at the following locations:

1. Medway Selectman's Office, Town Hall, Medway, MA 02053.

2. Medway Public Library, Medway, MA 02053.

3. Holliston Selectman's Office, Town Hall, Holliston, MA 01746.

4. Holliston Public Library, Holliston, MA 01746.

5. Hopkinton Selectman's Office, Town Hall, Hopkinton, MA 01748.

6. Hopkinton Public Library, Hopkinton, MA 01748.

Additional information on environmental matters concerning the proposal is available from Mr. Kenneth Frye, telephone (202) 357-9039.

Lois D. Cashell,
Acting Secretary.

[FR Doc. 87-27875 Filed 12-3-87; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. C188-55-000 et al.]

**Phillips Petroleum Co. et al.;
Applications for Certificates,
Abandonments of Service and
Petitions to Amend Certificates ¹**

December 1, 1987.

Take notice that each of the Applicants listed herein has filed an

¹ This notice does not provide for consolidation for hearing of the several matters covered herein.

application or petition pursuant to section 7 of the Natural Gas Act for authorization to sell natural gas in interstate commerce or to abandon service as described herein, all as more fully described in the respective applications and amendments which are on file with the Commission and open to public inspection.

Any person desiring to be heard or to make any protest with reference to said applications should on or before December 15, 1987, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in any proceeding herein must file a petition to intervene in accordance with the Commission's rules.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicants to appear or to be represented at the hearing.

Lois D. Cashell,
Acting Secretary.

Docket No. and date filed	Applicant	Purchaser and location	Price per Mcf	Pressure base
C188-55-000, A, Oct. 26, 1987.	Phillips Petroleum Co., 990-G Plaza Office Bldg., Bartlesville, Okla. 74004.	Various Purchasers, East Cameron Block 38 and 195, South Marsh Island Blocks 234 and 235, and Eugene Island Block 256, Offshore Louisiana.	(¹)	
C188-68-000 (C169-949)do.....	Sea Robin Pipeline Company, East Cameron Block 195, Offshore Louisiana.	(²)	
(C179-438)do.....	Sea Robin Pipeline Company, South Marsh Island Block 234 and 235, Offshore Louisiana.		
(C180-174)do.....	Sea Robin Pipeline Company, East Cameron Block 38, Offshore Louisiana.		
(C180-451), B, Oct. 26, 1987 ³do.....	Sea Robin Pipeline Company, Eugene Island Block 256, Offshore Louisiana.		
C188-124-000 (C166-625), B, Nov. 2, 1987.	Mesa Operating Limited Partnership, P.O. Box 2009, Amarillo, Texas 79189-2009.	Northern Natural Gas Company, Division of Enron Corp., Streeter GU #1-15 Sec. 15-T35S-R3W5, Gooch Field, Stevens County, Kansas.	(⁴)	
C188-127-000 (C166-977), B, Nov. 2, 1987.do.....	Northern Natural Gas Company, Division of Enron Corp., Albert #1-15 Sec. 5-T28N-R21W, N.E. Lovedale Field, Harper County, Oklahoma.	(⁴)	
C188-129-000 (C162-1210), B, Nov. 2, 1987.do.....	Northern Natural Gas Company, Division of Enron Corp., Wilson #2-44 Erick #1-44 Sec. 44, Blk. 43 H&TC Survey, Hodges Field, Roberts County, Texas.	(⁴)	
C188-132-000 (C168-1289), B, Nov. 2, 1987.do.....	Northern Natural Gas Company, Division of Enron Corp., Clancy #1-15 Sec. 10 & 15-6N-18ECM, Gooch Field, Texas County, Oklahoma.	(⁴)	

Docket No. and date filed	Applicant	Purchaser and location	Price per Mcf	Pressure base
CI88-134-000 (G-19968), B, Nov. 2, 1987.do.....	Northern Natural Gas Company, Division of Enron Corp., Frazier #1-4 Sec. 5, Blk. 1, C.I.F. Survey, Bernstein Field, Hansford County, Texas.	(⁴)
CI88-135-000 (G-19968), B, Nov. 2, 1987.do.....	Northern Natural Gas Company, Division of Enron Corp., Frazier #1-4 Sec. 4, Blk. 1, C.I.F. Survey, Bernstein Field, Hansford County, Texas.	(⁴)
CI88-136-000 (G-19967), B, Nov. 2, 1987.do.....	Northern Natural Gas Company, Division of Enron Corp., Frazier #1-3 Sec. 2 & 3, Blk. 1, C.I.F. Survey, Bernstein Field, Hansford County, Texas.	(⁴)
CI88-83-000 (G-12702), B, Nov. 2, 1987.do.....	Natural Gas Pipeline Company of America, Talley #1-16, Sec. 16: N ½ Block 2, I&GN Ry. Co. Survey, Quinduno Field, Roberts County, Texas.	(⁴)
CI88-128-000 (CI67-361), B, Nov. 2, 1987.do.....	Natural Gas Pipeline Company of America, Oil Development Company #1-38 All of Section 38, Blk. 4-T, T&NO Ry. Co. Survey, Upper Morrow Field, Hansford County, Texas.	(⁴)
CI88-130-000 (G-12238), B, Nov. 2, 1987.do.....	Natural Gas Pipeline Company of America, Cowan #1 SE/4 Sec. 198, Blk. M-2 BS&F Survey and Cowan A #1, SW/4 Sec. 195, Blk. M-2 BS&F Survey, Quinduno Field, Roberts County, Texas.	(⁴)
CI88-131-000 (CI68-625), B, Nov. 2, 1987.do.....	ANR Pipeline Company, Leachman #1-19 Sec. 19-T20N-R17W, Richland Field, Woodward County, Oklahoma.	(⁴)
CI88-133-000 (CI69-594), B, Nov. 2, 1987.do.....	Panhandle Eastern Pipe Line Company, Hart #1-4 S/2 Sec. 4, Blk. 3, PS&L Survey, W/2 Sec. 126, Blk. 45, H&TC Survey, Hansford-Lower Morrow Field, Hansford County, Texas.	(⁴)
CI88-137-000 (CI80-71-000), B, Nov. 18, 1987.	TXP Operating Co., P.O. Box 1396, Houston, Texas 77251.	ANR Pipeline Company, High Island Block 273, Offshore Texas.	(⁵)
CI88-138-000 (CI80-57-000), B, Nov. 18, 1987.do.....	United Gas Pipe Line Company, High Island Block 273, Offshore Texas.	(⁵)
CI88-139-000 (CI80-32-000), B, Nov. 18, 1987.do.....	Transcontinental Gas Pipe Line Corp., High Island Block 273, Offshore Texas.	(⁵)

¹ Applicant requests permanent blanket certificate with pregranted abandonment to sell gas subject to the abandonment application in Docket No. CI88-68-000 in interstate commerce to various purchasers. Applicant also requests waiver of Part 154 as to the establishment and maintenance of rate schedules and Sections 154.94(h) and (k).

² Applicant requests permanent abandonment of sales of gas to Sea Robin. In support of the application Applicant states that the parties have executed a settlement agreement which terminates the subject contract. Applicant agreed to waive all take-or-pay, minimum take, price and any other existing contract claims with Sea Robin. Deliverability is approximately 32,715 Mcf/d. The gas is NGPA section 102(d) and 104 post-1974 gas.

³ Additional material was received on November 17, 1987.

⁴ By Assignment and Conveyance, executed on 12-23-85, effective 9-1-85, Mesa Petroleum Co. assigned certain acreage to Kaiser-Francis Oil Company.

⁵ The lease dedicated under the gas purchase contract has expired. The reserves are depleted and all wells will be plugged and abandoned. Filing Code: A—Initial Service. B—Abandonment. C—Amendment to add acreage. D—Amendment to delete acreage. E—Total Succession. F—Partial Succession.

[FR Doc. 87-27876 Filed 12-3-87; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. EL88-2-000]

Safe Harbor Water Power Corp.; Order Instituting Investigation and Establishing Hearing Procedures

Issued: December 1, 1987.

Before Commissioners: Martha O. Hesse, Chairman; Anthony G. Sousa, Charles G. Stalon, Charles A. Trabandt and C. M. Naeve.

Safe Harbor Water Power Corporation (Safe Harbor), a single asset utility, which is a subsidiary of the

Baltimore Gas & Electric Company (BG&E) and the Pennsylvania Power and Light Company (PP&L), ¹ has on file with the Commission a formula rate. The formula rate includes an overall rate of return only. Separate cost of capital components are not specified. The existing overall return of 13.25% was accepted in Docket No. ER82-763-000.² Based on Safe Harbor's then-effective

¹ Safe Harbor owns a hydro-electric project on the Susquehanna River and sells the output to its parents, BG&E and PP&L.

² Letter order approving settlement agreement issued by the Commission on May 2, 1983. 23 FERC ¶ 61,207 (1983).

capitalization, the overall return was expected to yield an equity return of 15.83%.³ However, the equity return actually generated by the overall return will vary as the components (capital ratios and debt cost) of Safe Harbor's capitalization vary. Based on current capitalization and debt cost data, it appears that the current overall return of 13.25% yields a 19.88% return on equity. The major change in the capitalization appears to have been a significant reduction in the cost of debt. Since fewer dollars generated by the

³ *Id.*

13.25% overall return are needed to pay debt costs, the monies are available to the stockholders, increasing the equity return earned.

Moreover, we note that during the last year the cost of capital has decreased significantly.⁴ As a result, the Commission believes that the overall rate of return and the equity return derived therefrom, identified above, may result in unjust and unreasonable rates. The Commission believes that it is appropriate to institute a proceeding under section 206 of the Federal Power Act, 16 U.S.C. 824e (1982), to determine whether the rates are unjust and unreasonable and, if so, to establish just and reasonable rates.

Under current Commission precedent, formula raters may be designed to automatically track all cost changes, except changes in the equity return, without the necessity of a filing pursuant to Part 35 of the Commission's regulations, 18 CFR Part 35 (1987). Automatic changes in the equity return component have not been allowed because this aspect of a utility's rates requires an assessment of market conditions.⁵ However, this results in formula rates not properly tracking equity costs. In view of this and of the fact that rate relief with respect to the equity return component of formula rates is available only on a prospective basis under section 206 of the Federal Power Act, a modification in formula rates may be appropriate. Since formula rates require waiver of the notice and review provisions of the Federal Power Act, the Commission wishes to consider, in the hearing ordered herein, whether it should henceforth condition the use of Safe Harbor's formula rates upon a requirement that the company periodically justify its equity return component under a procedure which affords refund protection. Accordingly, the parties shall also address this issue.

Any person desiring to be heard should file a protest or motion to intervene with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC

⁴ For example, the Commission's Generic Rate of Return on Common Equity has decreased from 13.68% to 12.27%.

20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211 and 385.214 (1987). All such protests or motions should be filed within 10 days of the date of issuance of this order.

The Commission orders:

(A) Pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by section 402(a) of the Department of Energy Organization Act and by the Federal Power Act, particularly section 206 thereof, and pursuant to the Commission's Rules of Practice and Procedure and the regulations under the Federal Power Act, 18 CFR Chapter I, a public hearing shall be held concerning the justness and reasonableness of Safe Harbor's formula rate.

(B) A Presiding Administrative Law Judge, to be designated by the Chief Administrative Law Judge, shall convene a prehearing conference in this proceeding within approximately 10 days of the date of issuance of this order, in a hearing room of the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. The presiding judge is authorized to establish procedural dates which will permit an initial decision to be issued no later than March 18, 1988 and to rule on all motions (except motions to dismiss) as provided in the Commission's Rules of Practice and Procedure.

(C) The parties are hereby directed to file briefs on exceptions within 14 days of the initial decision and briefs opposing exceptions within 14 days of the filing of briefs on exceptions.

(F) The Secretary shall cause this order to be promptly published in the Federal Register.

By the Commission.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 87-27907 Filed 12-3-87; 8:45 am]

BILLING CODE 6717-01-M

⁵ See New England Power Company, 31 FERC ¶ 61,378 (1985); Southwestern Electric Power Company, 31 FERC ¶ 61,369 (1985).

[Docket No. C177-69-001 et al.]

Tenneco Oil Co.; Application

November 30, 1987.

Take notice that on November 10, 1987, Tenneco Oil Company (Applicant), of P.O. Box 2511, Houston, Texas 77001, filed an application pursuant to section 7 of the Natural Gas Act and Part 157 of the Commission's Regulations for a Certificate of Public Convenience and Necessity as successor-in-interest to Tenneco Exploration, Ltd., for authorization to continue sales and delivery of natural gas previously authorized by the Commission to various purchasers, all as more fully shown on the attached Exhibit "I". Tenneco Oil Company also requests redesignation of the rate schedules of Tenneco Exploration, Ltd., as those of Tenneco Oil Company, as shown on the attached Exhibit "I". This application is on file with the Commission and open to public inspection.

By an Assignment dated November 10, 1986 and effective October 31, 1986, Tenneco Oil Company acquired these properties from Tenneco Exploration, Ltd.

Any person desiring to be heard or to make any protest with reference to said application should be or before December 15, 1987, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in any proceeding herein must file a petition to intervene in accordance with the Commission's rules.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or to be represented at the hearing.

Lois D. Cashell,

Acting Secretary.

EXHIBIT I.—TENNECO OIL COMPANY SUCCESSOR-IN-INTEREST TO TENNECO EXPLORATION, LTD. CONTRACTS

TEL RS #	TEL GSC #	Contract date	Docket No.	Block	Purchaser	TOC W.I. estimated sales volume MCF/Mo.	Delivery point
9	921	10/7/68	CI 77-69	EI 208	ANR Pipe Line Company.....	60,000	Tenneco Oil's existing production platform in EI 208.
13	1043	5/18/78	CI 78-807	SS 169	Tennessee Gas Pipeline.....	9,900	Valve on inlet side of Buyer's facilities located on Ship Shoal Block 182 "C" Platform.
15	885	2/26/76	CI 79-282	WC 643	Tennessee Gas Pipeline.....	595,000	Inlet side of purchaser meter on "A" Platform.
16	897	4/23/76	CI 79-284	WC 642	Columbia Gas Trans.....	392,490	Inlet side of purchase meter on "A" Platform.
20	1253	9/07/79	CI 79-643	EC 353	Tennessee Gas Pipeline.....	123,600	Inlet side of "A" Platform.
22	969	5/18/77	CI 80-39	WC 643	Tennessee Gas Pipeline.....	600,000	Inlet side of measuring station on "B" Platform.
23	968	5/19/77	CI 80-40	EC 370/371	Columbia Gas Trans.....	600,000	Inlet side of measuring station on "B" Platform.

[FR Doc. 87-27877 Filed 12-3-87; 8:45 am]

BILLING CODE 6717-01-M

Office of Hearings and Appeals

Cases Filed; Week of October 2 through October 9, 1987

During the Week of October 2 through October 9, 1987, the appeals and applications for relief listed in the

Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy. Submissions inadvertently omitted from earlier lists have also been included.

Under DOE procedural regulations, 10 CFR Part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of

the regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, DC 20585.

George B. Breznay,
Director, Office of Hearings and Appeals.
November 25, 1987.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Week of October 2 through October 9, 1987]

Date	Name and Location of Applicant	Case No.	Type of Submission
May 2, 1987.....	Kenneth Walker, Abilene, TX.....	KRZ-0070	Interlocutory. If granted: The December 23, 1986, decision and order (Case Nos. KRR-0011, KRR-0012, KRZ-0047, KRZ-0048 and KRZ-0052) issued to Kenneth Walker which denied Mr. Walker's motion for reconsideration concerning his estoppel and laches defenses would be modified to permit the entertainment of those two defenses again.
Do.....	Kenneth Walker, Abilene, TX.....	KRZ-0072	Interlocutory. If granted: The interest provisions contained in the October 16, 1984, proposed remedial order issued to Southwestern States Marketing Corporation and Kenneth Walker would be stricken.
Do.....	Kenneth Walker, Abilene, TX.....	KRR-0034	Request for modification/rescission. If granted: The November 21, 1987, decision and order issued to Southwestern States Marketing Corp. and the Economic Regulatory Administration (Case Nos. KRD-0013, KRR-0013, and KRZ-0046) would be modified in so far as it relates to the time period for which Kenneth Walker may be liable for interest accruing on any principal violation amount.
Aug. 5, 1987.....	Boise Cascade Corp., Boise, ID.....	RR271-6	Request for modification/rescission in the stripper well refund proceeding. If granted: The March 9, 1987, determination (Case No. RF271-175) would be modified regarding Boise Cascade Corp.'s application for refund as a rail and water transporter in the stripper well litigation proceeding.
Aug. 17, 1987.....	Economic Regulatory Administration, Abilene, TX.....	KRZ-0071	Interlocutory. If granted: The October 16, 1984, proposed remedial order issued to Southwestern States Marketing Corp. and Kenneth Walker would be amended so as to decrease the alleged total violations amount and to substitute certain attachments for other attachments originally appended to the proposed remedial order.
Oct. 1, 1987.....	Glen Milner, Seattle, WA.....	KFA-0127	Appeal of an information request denial. If granted: The September 3, 1987, freedom of information request denial issued by the Albuquerque Operations Office would be rescinded and Glen Milner would receive access to documents concerning the shipment of nuclear warheads.
Oct. 5, 1987.....	Delgado Oil Co., Pinedale, WY.....	KEE-0155	Exception to the reporting requirements. If granted: Delgado Oil Company would no longer be required to file form EIA-782B "Resellers/Retailers' Monthly Petroleum Product Sales Report."
Do.....	Stephen Quakenbush, Albuquerque, NM.....	KFA-0126	Appeal of an information request denial. If granted: The September 29, 1987, freedom of information request denial issued by the Albuquerque Operations Office would be rescinded and Stephen Quakenbush would receive access to the administrative review file, which was compiled in connection with his lawsuit against the DOE.
Oct. 6, 1987.....	Coalition for Safe Power, Portland, OR.....	KFA-0128	Appeal of an information request denial. If granted: The September 17, 1987 freedom of information request denial issued by the Assistant Secretary for Environment, Safety, and Health would be rescinded and Coalition for Safe Power would receive access to a copy of the working papers for the Environmental Survey Preliminary Report for the Hanford site dated February 7, 1987.
Oct. 9, 1987.....	Indiana, Indianapolis, IN.....	KEG-0019	Petition for special redress. If granted: The Office of Hearings and Appeals would review three proposed expenditures for the stripper well funds which were disapproved by the Assistant Secretary for Conservation and Renewable Energy.

Date received	Name of refund proceeding/ name of refund applicant	Case No.	Date received	Name of refund proceeding/ name of refund applicant	Case No.	Date received	Name of refund proceeding/ name of refund applicant	Case No.
1/21/87.....	Research Fuels, Inc.	RF250-2789	10/1/87.....	Greencastle-Antrim School Dist.	RF297-5	10/2/87	Gulf Oil Refund Applications Received.	RF300-944 thru RF 300-1676
5/1/87.....	Gentz Petroleum Co.	RF265-2575	10/1/87.....	California & Hawaiian Sugar.....	RF271-233	10/5/87.....	Barge Transport.....	RF271-234
6/24/87.....	Chets Skelly Service.....	RF265-2574	10/1/87.....	Home Petroleum.....	RF212-3	10/5/87.....	Supreme Petroleum Co. of NJ.	RF303-2
8/19/87.....	Remsen Tank Line Co., Inc.....	RF225-10916	10/2/87.....	Orrick Gas Co.....	RF299-18			
9/10/87.....	Stewart Oil Co.....	RF265-2581	10/2/87	Crude Oil Refund Applications Received.	RF272-7360 thru RF272-7773			
9/28/87.....	Amoco Corporation.....	RF303-1				10/5/87.....	Chal-Lee Getty Service Center.	RF265-2559
10/1/87.....	State Escrow Distribution.....	RF302-1						
10/1/87.....	Western Petroleum Co.....	RF265-2558						

Date received	Name of refund proceeding/ name of refund applicant	Case No.
10/5/87	Chat-Lee Getty Service Center	RF265-2560
10/5/87	Jim's Skelly	RF265-2561
10/5/87	Richardson Automotive Skelly	RF265-2562
10/5/87	McDowells Skelly Service	RF265-2563
10/5/87	McDowells Skelly Service	RF265-2564
10/5/87	Dyer's Skelly Service	RF265-2565
10/5/87	Dyer's Skelly Service	RF265-2566
10/5/87	Harper Skelly	RF265-2567
10/5/87	Richard Jones Downtown Skelly	RF265-2568
10/5/87	Gunnels Skelly Service	RF265-2569
10/5/87	Joe's Getty	RF265-2570
10/5/87	Kerns Skelly	RF265-2571
10/5/87	Rush Enterprises	RF265-2572
10/5/87	B and T Skelly	RF265-2573
10/5/87	F.H. Whitman Oil Co., Inc.	RF299-17
10/7/87	Portland Heating Oil Co.	RF303-3
10/7/87	John W. Waterhouse	RF277-88
10/7/87	Shippensburg Area School Dist.	RF297-6
10/8/87	Leonard A. Marshand	RF250-2739
10/13/87	Ellex Transportation	RF270-2492
10/13/87	Johnson City Unified Wastewater	RF299-22
10/14/87	Joseph W. Lamecker	RF265-2576
10/15/87	Steele's Inc.	RF299-23
10/20/87	Kirby's Mobile	RF225-10915

[FR Doc. 87-27828 Filed 12-3-87; 8:45 am]

BILLING CODE 6450-01-M

Issuance of Decisions and Orders; Week of October 12 Through October 16, 1987

During the week of October 12 through October 16, 1987, the decisions and orders summarized below were issued with respect to applications for exception or other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Remedial Order

Gulfport Oil Co., 10/14/87; HRO-0229

Gulfport Oil Company objected to a Proposed Remedial Order which the ERA issued to the firm on April 4, 1984. After considering the firm's objections, the DOE found that Gulfport violated the layering regulations set forth in 10 CFR 212.186 by reselling crude oil without providing the services traditionally and historically associated with the resale of crude oil. The DOE therefore concluded that the Proposed Remedial Order should be issued as a final order and directed Gulfport to remit \$615,724.92 plus interest to the DOE.

Requests for Exception

Coble Oil Co. and Jim Woods Marketing Co., 10/14/87; KEE-0146 and KEE-0148

Coble Oil Company and Jim Woods Marketing Company filed Applications for Exception from the requirement to

submit Form EIA-782B, entitled "Resellers'/Retailers' Monthly Petroleum Product Sales Report." Each company was identified as a "certainty company" because it does business in four or more states. In considering the applicants' requests, the DOE found that neither firm demonstrated that it was affected in a particularly adverse manner by the filing requirement, or that its filing burden outweighed the especially strong public interest in obtaining the firm's data. Accordingly, both Applications for Exception were denied.

Deaton Oil Co., 10/15/87; KE-0152

Deaton Oil Company filed an Application for Exception from the requirement that it file Form EIA-782B, entitled "Resellers'/Retailers' Monthly Petroleum Product Sales Report." Deaton Oil is in the midst of bankruptcy proceedings and has reduced its staff. Furthermore, because the records of the company are currently being reviewed by an accountant, the President of Deaton Oil, Mr. J.D. Beavert, has limited access to them. The DOE concluded that Deaton Oil's lack of personnel and its inability to obtain the company records result in a significant burden which exceeds the burden normally associated with the completion of Form EIA-782B. Consequently, the DOE granted Deaton Oil permanent relief from the requirement to file Form EIA-782B.

Le Paul Oil Co., Inc., 10/15/87, KEE-0147

Le Paul Oil Company, Inc. filed an Application for Exception from the requirement that it file Form EIA-782B, entitled "Retailers'/Resellers' Monthly Petroleum Product Sales Report." In evaluating the request, the DOE found that the firm, a "certainty company," had not shown that its personnel turnover rendered the filing requirement a hardship, inequity, or unfair distribution of burdens which outweighed the public interest in obtaining the EIA-782B survey data. Accordingly, the exception request was denied.

Requests for Modification and/or Rescission

Kentucky, 10/15/87, KER-0032

The DOE issued a Decision and Order regarding a Motion for Reconsideration filed by the Commonwealth of Kentucky. The Commonwealth's Motion sought reconsideration of a DOE denial of a Petition for Special Redress that the Commonwealth filed on June 12, 1987. *Kentucky*, 16 DOE ¶ 82,504 (1987) (*Kentucky*). In *Kentucky*, the DOE concluded that the Commonwealth's

proposal to place all of its Stripper Well funds in a Low Income Energy Assistance Trust Fund ("the Trust Fund") was not consistent with the terms of the Stripper Well Settlement Agreement. In denying the Commonwealth's Motion for Reconsideration of *Kentucky*, the DOE found that overall balance in a State's restitutionary plan and timely restitution were indeed criteria by which the DOE could evaluate Petitions for Special Redress relating to State use of Stripper Well funds. Specifically, the DOE determined that the Trust Fund does not constitute a balanced restitutionary plan. More important, the DOE reaffirmed that because the Trust Fund does not provide for timely restitution, it fails to fulfill a fundamental purpose of restitution, i.e., to distribute benefits to the class of persons that most closely corresponds to the class that experienced injury. Accordingly, the Motion for Reconsideration was denied.

Refund Applications

A. Tarricone, Inc./Wyatt, Inc., 10/16/87, RF155-4

Wyatt, Inc. filed an Application for Refund seeking a portion of the funds remitted by A. Tarricone, Inc. pursuant to a consent order with the DOE. Wyatt's claim was based on its purchases of A. Tarricone's No. 2 heating oil on the spot market. The DOE noted the presumption that a reseller who made only spot purchases was not injured, and, therefore, does not qualify for a refund. The DOE further noted that Wyatt was afforded an opportunity to rebut the no-injury presumption by demonstrating that the purchases were made to maintain supplies to base period customers, and that the firm sustained losses as a result of the purchases. The DOE held that Wyatt failed to rebut the no-injury presumption. The firm's refund request was therefore denied.

Arizona Public Service Co., 10/16/87, RF270-1522

The DOE issued a Decision and Order denying an Application for Refund from the Surface Transporters Escrow that was established as a result of the Stripper Well Settlement Agreement. The DOE noted that a Surface Transporters applicant must waive its claim to refunds from the seven other M.D.L. 378 escrows and that the Arizona Public Service Company had received a refund from the Utilities Escrow Account. As a result, the DOE determined that the firm's Surface Transporters waiver was invalid and that the firm was ineligible to receive a

refund from the Surface Transporters Escrow.

Catawba Rental Co., Inc., 10/15/87, RF270-1061

The DOE issued a Decision and Order denying an Application for Refund from the Surface Transporters Escrow established as a result of the Stripper Well Settlement Agreement. The Applicant leased vehicles to independent transportation companies during the Settlement Period. The DOE determined that as a rental company, the Applicant owned the vehicles, but did not operate them for surface transportation. When the gallons used in these vehicles were excluded from the Applicant's claim, the remaining volume of purchases for the Applicant's private fleet of service vehicles was below the 250,000 minimum gallon threshold. Therefore, the Application was denied.

Clark Trucking Service, Inc. 10/13/87, RF270-1070

The DOE issued a Decision and Order denying an Application for Refund from the Surface Transporters Escrow established as a result of the Stripper Well Settlement Agreement. Owner-operator gallons were excluded from the claim because the applicant did not demonstrate that it purchased the fuel and that it was not reimbursed specifically for any such purchases. After the owner-operator purchase volumes were subtracted, the Applicant's claim was below the 250,000 minimum gallon threshold. Therefore, the Application was denied.

Dorchester Gas Corp./ Cimarron Valley, Inc. Curt's Oil Co., Inc., 10/16/87, RF253-29 and RF253-13

The DOE issued a Decision and Order approving two Applications for Refund in the Dorchester Gas Corporation refund proceeding. The two claimants demonstrated that they were direct purchasers of Dorchester covered products during the consent order period. Each applicant elected to limit its claim to the \$5,000 small claims threshold. Thus, the claimants were not required to demonstrate injury, and a small claims refund of \$5,000 in principal and \$1,556 in interest was approved for each of the two applicants.

Ellex Transportation, Inc., 10/16/87, RF270-2492

The DOE issued a Decision and Order revising a previous Decision and Order which granted refunds to several applicants in the Surface Transporters refund proceeding. *Blincoe Trucking Co.*, 16 DOE ¶ 85,133 (1987) (*Blincoe*). The DOE found that the volume approved for one of the applicants, Ellex

Transportation, Inc. (*Ellex*) (Case No. RF270-398), was incorrect. Specifically, the DOE found that Ellex included in its claimed purchase volumes diesel fuel purchased by owner-operators hired by the firm during the Settlement Period. Since Ellex did not actually purchase the fuel used by its owner-operators, it is ineligible to receive a refund based upon these volumes. See *Aero Trucking Inc.*, 16 DOE ¶ 85,239 (1987). The DOE therefore modified *Blincoe* to reduce the volume approved for Ellex from 17,570,000 to 7,409,471.

Getty Oil Co./Celanese Chemical Co., Inc., 10/14/87, RF265-2548

The DOE issued a Decision and Order concerning an Application for Refund filed by Celanese Chemical Company, Inc. (Celanese), an end-user of a product covered by a consent order that the DOE entered into with Getty Oil Company. Celanese submitted information indicating the volume of Getty butane that it purchased during the consent order period. As an end-user, Celanese is entitled to receive the full volumetric refund. The total amount of the refund approved in this Decision is \$841,486, representing \$419,506 in principal and \$421,980 in accrued interest.

Getty Oil Co./Ehlwen Service Station et al., 10/15/87, RF265-2201 et al.

The DOE issued a Decision and Order concerning 13 Applications for Refund filed by resellers or retailers of products covered by a consent order that the DOE entered into with Getty Oil Company. Each applicant submitted information indicating the volume of its Getty purchases. In ten of these cases, the applicants were eligible for a claim below the \$5,000 threshold. In the remaining three cases, the applicants elected to limit their claims to \$5,000. The total amount of the refunds approved in this Decision is \$70,005, representing \$34,901 in principal and \$35,104 in accrued interest.

Getty Oil Co./Krouse Fuel Co., et al., 10/15/87, RF265-136 et al.

The DOE issued a Decision and Order concerning 71 Applications for Refund filed by resellers or retailers of products covered by a consent order that the DOE entered into with Getty Oil Company. Each applicant submitted information indicating the volume of its Getty purchases. In 23 of these cases, the applicants were eligible for a claim below the \$5,000 threshold. In the remaining 48 cases, the applicants elected to limit their claims to \$5,000. The total amount of the refunds approved in this Decision is \$272,251,

representing \$135,723 in principal and \$136,528 in accrued interest.

Gulf Oil Corp./Beals' Variety Store, Blue Ridge Trucking Co., Inc., 10/16/87, RF300-254 and RF300-255

The DOE issued a Decision and Order approving the Applications for Refund filed by Beals' Variety Store and Blue Ridge Trucking Company, Inc. from a consent order fund made available by Gulf Oil Corporation. Since the Beals' refund claim was for an amount below the \$5,000 small claims threshold, it was not required to demonstrate injury in order to receive a refund. Beals' refund was \$680, including \$573 in principal and \$107 in interest. As an end-user of Gulf refined petroleum products, Blue Ridge was eligible for a refund of its full allocable share without a demonstration of injury. Blue Ridge's refund was \$527, including \$444 in principal and \$83 in interest.

Hub Truck Rental Corp., 10/15/87, RF270-367

The DOE issued a Decision and Order in connection with its administration of the \$10.75 million escrow fund established for Surface Transporters pursuant to the Settlement Agreement in the DOE Stripper Well Exemption Litigation. Hub is a truck rental and leasing company which purchased over 250,000 gallons of petroleum products during the Settlement Period. A portion of Hub's business involved the rental of vehicles alone while the remainder involved the rental of vehicles with drivers furnished by Hub. In the latter type of operation, Hub functioned as an "owner-operator" of the lessor. The DOE determined that Hub is eligible for a refund with respect to the gallons of petroleum products which it purchased and consumed as an "owner-operator," but is ineligible for the remainder of its purchases which it resold to the persons who rented its vehicles alone. Accordingly, the DOE approved Hub's "owner-operator" volumes. The number of gallons approved in this Decision and Order is 4,157,187.

Hunsaker Truck Lease Inc., Mendon Leasing Corp., 10/14/87, RF270-31 and RF270-74

The DOE issued a Decision and Order concerning Applications for Refund filed by Hunsaker Truck Lease Inc., and Mendon Leasing Corp., from the \$10.75 million Surface Transporters Escrow fund established pursuant to the Settlement Agreement in the DOE Stripper Well Exemption Litigation. In analyzing the claims, the DOE found that the applicants' both leased trucks during the Settlement Period. Based

upon the definition of "Surface Transporter," which specifically excludes car rental companies, *Order Establishing Surface Transporters Escrow* ¶ 16, and case precedents involving truck rental firms, the applicants' Applications were denied.

Indianhead Truck Line, Inc., et al., 10/13/87, RF270-592 et al.

The DOE issued a Decision and Order in connection with its administration of the \$10.75 million escrow fund established for Surface Transporters pursuant to the Settlement Agreement in the DOE Stripper Well Exemption Litigation. The DOE approved the gallonages of refined petroleum products claimed by five transportation companies and will use those gallonages as a basis for the refund that will ultimately be issued to the five firms. The DOE stated that because the size of a surface transporter applicant's refund will depend upon the total number of gallons that are ultimately approved, the actual amounts of the five firms' refunds will be determined at a later date. The total gallonage approved in the Decision is 332,409,149.

Marathon Petroleum Co./Gulf States Oil & Refining Co., 10/15/87, RF250-1906

Gulf States Oil & Refining Company filed an Application for Refund in the Marathon Petroleum Company refund proceedings. Gulf States' refund claim was based on 20,370,429 gallons of covered products. The DOE noted that those gallons were obtained through exchanging products rather than actual purchases and that the DOE had provided Gulf States with an opportunity to show a likelihood of regulatory violation by Marathon in the exchange transactions. The DOE found that Gulf States had failed to do so. The DOE therefore denied Gulf States' refund request.

Marathon Petroleum Co./Norman Oil Co., Jacobus Co., 10/14/87, RF250-2498, RF 250-2499, RF250-2598 and RF250-2599

The DOE issued a Decision and Order concerning Applications for Refund filed on behalf of the Norman Oil Company and Jacobus Company and Jacobus Company in connection with the Marathon Petroleum Company special refund proceeding. Under the refund procedures established for Marathon applicants, Norman's and Jacobus' purchase volumes each corresponded to a volumetric share exceeding the \$5,000 small claims threshold level. Both Norman and Jacobus elected to limit their refund claims to \$5,000, and were therefore not required to submit a

detailed showing of injury. The sum of refunds approved in the Decision and Order is \$11,214, representing \$10,000 in principal and \$1,214 in interest.

Martin Oil Service, Inc./Schweigert Oil Co., Lain Hlado, Minuteman Gas & Pantry, 10/13/87, RF240-2, RF240-3 and RF240-23

The DOE issued a Decision and Order granting three Applications for Refund from the Martin Oil Service, Inc. escrow account. Each applicant was engaged in the resale of Martin motor gasoline. Each applicant elected to apply for a refund based upon the presumptions set forth in *Martin Oil Service, Inc.*, 14 DOE ¶ 85,059 (1986). The total amount of refunds approved in this determination is \$3,708 (\$2,503 principal plus \$1,205 interest).

Momsen Trucking Co., 10/16/87, RR270-19

The DOE issued a Decision and Order concerning Momsen Trucking Company's request for reconsideration of the determination in *Heartland Express, Inc. of Iowa*, 15 DOE ¶ 85,400 (1987), that Momsen was eligible for a Surface Transporter refund based upon purchases of 12,067,515 gallons of petroleum products during the Settlement Period. In the Motion, Momsen stated that the miles-per-gallon figure used to derive its original purchase volume estimate was erroneous and that its refund, when issued, should in fact be based upon purchases of 13,470,715 gallons of petroleum products during the Settlement Period. The DOE found that Momsen had provided evidence sufficient to warrant increasing its approved purchase volumes.

Accordingly, Momsen's Motion was granted, and the purchase volume upon which its refund will be based was increased to 13,470,715 gallons.

North American Van Lines, Inc. et al., 10/15/87, RF 270-1556 et al.

The DOE issued a Decision and Order approving the volumes of five Applications for Refund from the \$10.75 million escrow fund established for Surface Transporters pursuant to the Settlement Agreement in the DOE Stripper Well Exemption Litigation. In this Decision, three claims were adjusted to eliminate ineligible gallons, while one claim was adjusted to eliminate mathematical errors. The total number of gallons approved in this Decision and Order is 23,095,779.

Peter Pan Bus Lines, Inc. et al., 10/15/87, RF270-1624 et al.

The DOE issued a Decision and Order approving the volumes of nine Applications for Refund from the \$10.75

million escrow fund established for Surface Transporters pursuant to the Settlement Agreement in the DOE Stripper Well Exemption Litigation. In this Decision, two claims were adjusted to eliminate mathematical errors. The total number of gallons approved in this Decision and Order is 76,801,220.

Sears, Roebuck and Co., 10/15/87, RF270-1653

The DOE issued a Decision and Order regarding an Application for Refund from the Surface Transporters Escrow filed by Sears, Roebuck and Co. (Sears). In the Decision, the DOE noted that in addition to claiming a refund from the Surface Transporters Escrow, Sears had filed an application for a refund from the Retailers Escrow. Furthermore, payment to Sears from the Retailers Escrow appeared imminent. The DOE found that Sears had invalidated its Surface Transporter waiver by filing a refund claim from the Retailers Escrow. Accordingly, Sears' Surface Transporter claim was denied.

Tresler Oil Co./Imperial Refineries, Inc., 10/15/87, RF295-5

The DOE issued a Decision granting a refund from the Tresler Oil Company escrow account to a retailer of Tresler motor gasoline. The Applicant elected to apply for a refund based upon the presumptions set forth in the *Tresler* decision. *Tresler Oil Company*, 15 DOE ¶ 85,522 (1987). The DOE granted a refund of \$573 (\$502 principal and \$71 interest).

Dismissals

The following submissions were dismissed:

Company Name and Case No.

Apache Tank Line, Inc.—RF270-2409
 Carson Petroleum Company—RF240-22
 Dixie Hauling Company—RF270-2273
 Duane Sitfin—RF272-8422
 Ellsworth Freight Lines, Inc.—RF270-2260
 Emerson Transport, Inc.—RF270-2261
 ERA/GHR Energy Corporation—KES-0006
 Glen Milner—KFA-0124
 Illini Express, Inc.—RF270-2422
 International Drilling & Energy Corporation—RR208-1
 J.D. Streett & A., Inc.—KRZ-0067
 Major Transportation, Inc.—RF270-2252
 Mass Transportation, Inc.—RF270-2270
 Plymouth Rock Transportation—RF270-2282
 R.H. Crawford, Inc.—RF270-2430
 Simonik Moving & Storage, Inc.—RR270-6
 Southern Pacific Transportation Company—RR271-5

Steve D. Thompson Trucking, Inc.—
RF270-2407
Superior Oil Company—RF253-27
The Bulletin Company—RF225-6491

Copies of the full text of these decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals, Room 1E-234, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except federal holidays. They are also available in *Energy Management: Federal Energy Guidelines*, a commercially published loose leaf reporter system.

George B. Breznay,
Director, Office of Hearings and Appeals.
November 25, 1987.
[FR Doc. 87-27829 Filed 12-3-87; 8:45 am]
BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-3298-2]

Environmental Impact Statement and Regulations; Availability of EPA Comments

Availability of EPA comments prepared November 16, 1987 through November 20, 1987 pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 382-5075/76.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 24, 1987 (52 FR 13749).

Draft EISs

ERP No. D-NOA-A91054-00, Rating LO, Atlantic, Gulf and Caribbean Exclusive Economic Zones (EEZ) Billfish Fishery Management Plan, White and Blue Marlin, Sailfish, and the Longbill Spearfish, Implementation.

Summary: EPA has reviewed the document and has no objection to the action as proposed.

Final EISs

ERP No. FB-FHW-A4197-HI, Interstate H-3 Freeway Constitution, Halawa Interchange to Halekou Interchange, Reevaluation, Funding, 404 Permit, Island of Oahu, Honolulu County, HI.

Summary: The document addressed most concerns EPA raised regarding potential sole source aquifer impacts.

EPA indicated support for an FHWA geological survey to assess infiltration characteristics of North Halawa Stream.

ERP No. F-SCS-G36173-OK, Water-fall-Gilford Creek Watershed Flood Control and Agricultural Drainage, Construction, 404 Permit and Funding, McCurtain County, OK.

Summary: EPA has no objection to the proposed action as described.

Regulations

ERP No. RS-NOA-A01093-00, 15 CFR Part 971; Deep Seabed Mining; Regulations for Commercial Recovery and Revision of Regulations for Exploration; (Docket No. 50712-7186) (52 FR 34748).

Summary: EPA found that NOAA had addressed a majority of concerns expressed in EPA's comments on the previous version of the proposed regulations. EPA believes NOAA's adoption of the Ocean Discharge Criteria (of section 403(c) of the Clean Water Act) provides a cohesive regulatory structure for applicable permit requirements.

Dated: December 1, 1987.

Richard E. Sanderson,
Director, Office of Federal Activities.
[FR Doc. 87-27889 Filed 12-3-87; 8:45 am]
BILLING CODE 6560-50-M

[ER-FRL-3298-3]

Environmental Impact Statements; Availability

Responsible Agency: Office of Federal Activities, General Information (202) 382-5073 or (202) 382-5075.

Availability of Environmental Impact Statements filed November 23, 1987 Through November 27, 1987 Pursuant to 40 CFR 1506.9.

EIS No. 870428, Final, BLM, WY, Pinedale Resource Area, Resource Management Plan, Rock Springs District, Sublette and Lincoln Counties, Due: January 4, 1988, Contact: Joe Patti (307) 772-2226.

EIS No. 870429, Final, EPA, LA, Calcasieu River and Pass Ocean Dredged Material Disposal Site Designation for Material Dredged from the Calcasieu Channel System, Cameron Parish, Due: January 4, 1988, Contact: Norm Thomas (214) 655-6551.

EIS No. 870430, Draft, EPA, TX, Corpus Christi/Ingleside Ocean Dredged Material Disposal Site Designation for Material Dredged from the Corpus Christi Ship Channel in Conjunction with the U.S. Navy's Gulf Coast Strategic Homeport Project, Due:

January 18, 1988, Contact: Norm Thomas (214) 655-6651.

EIS No. 870431, FSUPPL, COE, LA, New Orleans to Venice Hurricane Protection Plan, Barrier Feature Construction, Plaquemines Parish, Due: January 4, 1988, Contact: E. Scott Clark (504) 862-2521.

EIS No. 870432, Final, BIA, CA, Colmac 45MW Biomass-Fueled, Power Plant, Construction and Operation, Lease Approval, Cabzon Indian Reservation, Riverside County, Due: January 4, 1988, Contact Maurice Babby (916) 978-4691.

Amended Notice

EIS No. 870406, Draft, AFS, OR, Fremont National Forest, Land and Resource Management Plan, Lake and Klamath Counties, Due: March 1, 1988, Published FR 11-27-87—Incorrect due date.
Dated: December 1, 1987.

Richard E. Sanderson,
Director, Office of Federal Activities.
[FR Doc. 87-27890 Filed 12-3-87; 8:45 am]
BILLING CODE 6560-50-M

[FRL-3298-8]

Science Advisory Board, Research Strategies Subcommittee, Risk Reduction Group; Open Meeting

Under Pub. L. 92-463, notice is hereby given that a meeting of the Risk Reduction Group of the Science Advisory Board's Research Strategies Subcommittee will meet Thursday, December 17, 1987, from 8:00 a.m. to 5:00 p.m. in Lewis Conference Room, Building 66-360, 25 Ames Street, Massachusetts Institute of Technology, Cambridge, Massachusetts.

The purpose of the meeting is to review the December 11, 1987, Draft Risk Reduction Group Report.

The meeting is open to the public. Any member of the public wishing to attend, make brief oral comments, or submit written comments to the Group should notify Mrs. Kathleen Conway, Executive Secretary, or Mrs. Dorothy Clark, Staff Secretary, (A101-F) Science Advisory Board, by the close of business on Friday, December 11, 1987. The telephone number is (202) 382-2552.

Dated: December 1, 1987.

Terry F. Yosie,
Director, Science Advisory Board.
[FR Doc. 87-27993 Filed 12-3-87; 8:45 am]
BILLING CODE 6560-50-M

[OPTS-62048F; FRL-3298-6]

Asbestos-Containing Materials in Schools; Announcement of Change in Technical Assistance Service**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Announcement of change in technical information service.

SUMMARY: The EPA Asbestos Technical Information Service previously offered through Research Triangle Institute (RTI) has now been combined with other technical information services offered by the Office of Toxic Substances. The answering service, which could be reached by dialing 1-800-334-8571, is no longer in operation. Callers are now requested to dial (202) 554-1401 for asbestos-related technical inquiries.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room E-543, 401 M Street SW., Washington, DC 20460, (202) 554-1404.

SUPPLEMENTARY INFORMATION: Since 1979, EPA has operated a telephone service to provide technical assistance for laboratories analyzing bulk samples for asbestos. This notice announces the consolidation of the service with others in order to provide more efficient responses for all persons calling on toxic substances matters. All callers should now direct technical inquiries to (202) 554-1404. The EPA has made arrangements to provide prompt response to all inquiries for technical assistance through this one telephone number.

Dated: November 24, 1987.

Charles L. Elkins,

Director, Office of Toxic Substances.

[FR Doc. 87-27867 Filed 12-3-87; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA-803-DR]

Federated States of Micronesia; Major Disaster and Related Determinations**AGENCY:** Federal Emergency Management Agency.**ACTION:** Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Federated States of Micronesia (FEMA-803-DR), dated November 25, 1987, and related determinations.

DATED: November 25, 1987.**FOR FURTHER INFORMATION CONTACT:**

Neva K. Elliott, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472 (202) 646-3614.

Notice: Notice is hereby given that, in a letter dated November 25, 1987, the President declared a major disaster under the authority of the Disaster Relief Act of 1974, as amended (42 U.S.C. 5121 *et seq.*, Pub. L. 93-288), as follows:

I have determined that the damage in certain areas of the Federated States of Micronesia resulting from Typhoon Nina beginning on or about November 21, 1987, is of sufficient severity and magnitude to warrant a major disaster declaration under Public Law 93-288. I, therefore, declare that such a major disaster exists in the Federated States of Micronesia.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under Pub. L. 93-288 for Public Assistance will be cost shared.

The time period prescribed for the implementation of section 313(a), priority to certain applications for public facility and public housing assistance, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Mr. David P. Grier, IV of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the Federated States of Micronesia to have been affected adversely by this declared major disaster:

The State of Truk for Individual Assistance and Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

Julius W. Becton, Jr.,

Director, Federal Emergency Management Agency.

[FR Doc. 87-27849 Filed 12-3-87; 8:45 am]

BILLING CODE 6718-02-M

[FEMA-802-DR]

Texas; Amendment to Notice of a Major-Disaster Declaration**AGENCY:** Federal Emergency Management Agency.**ACTION:** Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Texas [FEMA-802-DR], dated November 20, 1987, and related determinations.

DATED: November 30, 1987.**FOR FURTHER INFORMATION CONTACT:**

Neva K. Elliott, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3614.

Notice: The notice of a major disaster for the State of Texas, dated November 20, 1987, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of November 20, 1987:

The Counties of Leon and Madison for Individual Assistance only.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

Dave McLoughlin,

Deputy Associate Director, State and Local Programs and Support, Federal Emergency Management Agency.

[FR Doc. 87-27850 Filed 12-3-87; 8:45 am]

BILLING CODE 6718-02-M

FEDERAL MARITIME COMMISSION**Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation; Issuance of Certificate (Performance)**

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of section 3, Pub. L. 89-777 (80 Stat. 1357, 1358) and Federal Maritime Commission General Order 20, as amended (46 CFR Part 540): Travel Dynamics, Inc. and New Frontier Cruises, Ltd., 132 East 70th Street, New York, New York 10021.

Dated: December 1, 1987.

Joseph C. Polking,

Secretary.

[FR Doc. 87-27872 Filed 12-3-87; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM**Fentura Bancorp, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies**

The companies listed in this notice have applied for the Board's approval

under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 224.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than December 24, 1987.

A. Federal Reserve Bank of Chicago (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Fentura Bancorp, Inc., Fenton, Michigan*; to become a bank holding company by acquiring 100 percent of the voting shares of State Savings Bank of Fenton, Fenton, Michigan.

2. *Jasand Inc., Cedar Rapids, Iowa*; to become bank holding company by acquiring 81.98 percent of the voting shares of City National Bank of Cedar Rapids, Cedar Rapids, Iowa. Comments on this application must be received by December 21, 1987.

Board of Governors of the Federal Reserve System, November 30, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-27811 Filed 12-3-87; 8:45 am]

BILLING CODE 6210-01-M

NBD Bancorp, Inc.; Acquisition of Company Engaged in Permissible Non-banking Activities

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of

Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as a greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 23, 1987.

A. Federal Reserve Bank of Chicago (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *NBD Bancorp, Inc., Detroit, Michigan*; to acquire NBD Insurance Company, and thereby engage in acting as reinsurer for credit life and disability insurance related to extensions of credit made by NBD Bancorp, Inc., or its subsidiaries pursuant to § 225.25(b)(8) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, November 30, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-27812 Filed 12-3-87; 8:45 am]

BILLING CODE 6210-01-M

First Bancorp of Kansas; Formation of, Acquisition by, or Merger of Bank Holding Companies

The company listed in this notice has applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding

company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for the application or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Comments regarding this application must be received not later than December 18, 1987.

A. Federal Reserve Bank of Kansas City (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *First Bancorp of Kansas, Wichita, Kansas*; to acquire 100 percent of the voting shares of Haysville State Bank, Haysville, Kansas.

Board of Governors of the Federal Reserve System, December 2, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-28047 Filed 12-3-87; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Department of Health and Human Services (HHS) publishes a list of information collection packages it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). The following are those packages submitted to OMB since the last list was published on November 20, 1987.

Health Care Financing Administration

(Call Reports Clearance Officer on 301-594-1238 for copies of package)

1. **HMO Reporting Forms—NEW—** PROs are authorized to review inpatient and outpatient services for Section 1876

contracts for the quality of care provided, accessibility and underutilization and whether the setting for providing services is appropriate. *Respondents:* Businesses or other for-profit, Small businesses or organizations. *Number of Respondents:* 54; *Frequency of Response:* Occasionally; *Estimated Annual Burden:* 5,400 hours.

OMB Desk Officer: Allison Herron.

Family Support Administration

(Call Reports Clearance Officer on 202-245-0652 for copies of package)

1. Reporting Requirements for Targeted Assistance Grants for Services for Refugees and Entrants in Local Areas of High Need—0970-0042—This report is used to monitor service activities and expenditures of grant monies given to State agencies to place dependent refugees into unsubsidized employment. Data on the report is also tabulated and used to report program outcomes to the Congress. *Respondents:* State or local governments. *Number of Respondents:* 20; *Frequency of Response:* Twice per year; *Estimated Annual Burden:* 160 hours.

OMB Desk Officer: Elana Norden.

Public Health Services

(call Reports Clearance Officer on 202-245-2100 for copies of package)

Food and Drug Administration

1. Request for Certification or Testing of an Antibiotic Batch—0910-0007—The regulation provides procedures for manufacturers to use in requesting certification of an antibiotic batch if they wish to do so. *Respondents:* Businesses or other for-profit. *Number of Respondents:* 1; *Frequency of Response:* Occasionally; *Estimated Annual Burden:* 1 hour.

Alcohol, Drug Abuse and Mental Health Administration

1. Field Test of Survey Procedures and Forms for the 1989 National Institute for Mental Health (NIMH) Client Sample Survey of Outpatient Programs in Organized Mental Health Settings—NEW—This field test will assess the design, procedures, and forms for a proposed 1989 longitudinal survey. Sociodemographic, clinical, service, charges, and client functioning data will be collected to meet the information needs of NIMH, the Department, States, and researchers. *Respondents:* State or local governments, Businesses or other for-profit, Non-profit institutions, Small businesses or organizations. *Number of Respondents:* 2,070; *Frequency of Response:* One-time; *Estimated Annual Burden:* 1,498 hours.

OMB Desk Officer: Shanna Koss.

As mentioned above, copies of the information collection clearance packages can be obtained by calling the Reports Clearance Officer, on one of the following numbers:

HCFA: 301-594-1238

PHS: 202-245-2100

FSA: 202-245-0652

Written comments and recommendations for the proposed information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address: OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, DC 20503. ATTN: (name of OMB Desk Officer).

Date: November 30, 1987.

James F. Trickett,

Deputy Assistant Secretary, Administrative and Management Services.

[FR Doc. 87-27852 Filed 12-3-87; 8:45 am].

BILLING CODE 4150-04-M

Food and Drug Administration

[Docket No. 87M-0375]

Allergan Optical; Premarket Approval of Wet-N-Soak™ Wetting and Soaking Solution

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Allergan Optical, Irvine, CA, for premarket approval, under the Medical Device Amendments of 1976, of Wet-N-Soak™ Wetting and Soaking Solution for use in the chemical disinfection and storage of the 3M Fluoropolymer (flurofocon A) Contact Lens and hard contact lenses. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant of the approval of the application.

DATE: Petitions for administrative review by January 4, 1988.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David M. Whipple, center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7940.

SUPPLEMENTARY INFORMATION: On July 9, 1987, Allergan Optical, Irvine, CA 92715, submitted to CDRH an application for premarket approval of Wet-N-Soak™ Wetting and Soaking Solution. Wet-N-Soak™ Wetting and Soaking Solution is indicated for use in the chemical disinfection and storage of the 3M Fluoropolymer (flurofocon A) Contact Lens and hard contact lenses.

On July 24, 1987, the Ophthalmic Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On October 30, 1987, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact David M. Whipple (HFZ-460), address above.

The labeling of Wet-N-Soak™ Wetting and Soaking Solution states that the solution is indicated for use in the chemical disinfection and storage of the 3M Fluoropolymer (flurofocon A) Contact Lens and hard contact lenses. Manufacturers of the rigid gas permeable contact lenses that have been approved for marketing are advised that whenever CDRH published a notice in the Federal Register of approval of a new solution for use with an approved rigid gas permeable contact lens, the manufacturer of each lens shall correct its labeling to refer to the new solution at the next printing or at such other time as CDRH prescribes by letter to the applicant.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR

10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the *Federal Register*. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before January 4, 1988, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), 90 Stat. 554-555, 571 (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center and Devices and Radiological Health (21 CFR 5.53).

Dated: November 25, 1987

John C. Villforth,

Director, Center for Devices and Radiological Health.

[FR Doc. 87-27868 Filed 12-3-87; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO-010-08-4133-17]

Availability of Record of Decision (ROD) on Wolf Ridge Corp. Mine Plan for a Nahcolite Solution Mine

AGENCY: Bureau of Land Management (BLM), Interior.

ACTION: Notice of availability of record of decision.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969, BLM has prepared a ROD on Wolf Ridge Corporation's (WRC) mine plan for a nahcolite solution mine in the Piceance Basin, Rio Blanco

County, Colorado. The ROD records BLM's decision to approve WRC's mine plan (the Proposed Action), subject to BLM applied stipulations.

EFFECTIVE DATE: The ROD became effective with its signing on November 20, 1987, by Neil F. Morck, State Director for Colorado.

ADDRESS: Copies of the ROD are available upon request at the White River Resource Area Office, BLM, PO Box 928, Meeker, Colorado 81641.

FOR FURTHER INFORMATION CONTACT: B. Curtis Smith, Area Manager, at the above address. Telephone: (303) 878-3601.

SUPPLEMENTARY INFORMATION: BLM completed an environmental impact statement (EIS) on WRC's mine plan for a commercial nahcolite solution mine within existing sodium leases they hold in northwest Colorado. WRC's proposal involves phased-approach development with initial production of nahcolite at a rate of 50,000 tons/year increasing in the second or third year to a maximum production of 125,000 tons/year. The proposed 30-year project includes a well field for in situ solution mining of nahcolite; a handling and processing plant, including evaporation ponds; and associated transportation, access, and support facilities.

The EIS analyzed the environmental and socioeconomic impacts of the Proposed Action and three project alternatives. It also identified mitigative measures and stipulations that are incorporated into the approved plan to (1) alleviate or minimize potential environmental impacts from their proposal, and (2) ensure compliance of their proposal with existing sodium lease terms.

Decision

The decision is to approve the Proposed Action, subject to BLM applied stipulations.

Mitigation and Monitoring

All practicable means to avoid or minimize environmental harm from WRC's proposal (Proposed Action) have been adopted into BLM's approval.

Neil F. Morck,

State Director.

Dated: November 20, 1987.

[FR Doc. 87-27618 Filed 12-3-87; 8:45 am]

BILLING CODE 4310-J8-M

[UT-020-08-4212-14; U-61689]

Salt Lake District; Intent to Amend Box Elder Resource Management Plan; Lands Program Decision 2

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: The Bureau of Land Management (BLM) Salt Lake District proposes to amend Lands Program Decision 2 of the Box Elder Resource Management Plan (RMP). The amendment would add two 40 acre tracts to the list of tracts in the plan that were identified for disposal by an appropriate method under the law. The tracts are described as follows:

T. 13N., R. 13W., SLM

Section 31, Lot 1

T. 11N., R. 18W., SLM

Section 10, SE¼NW¼

Issues to be addressed include minor loss of native vegetation and associated wildlife habitat. An environmental assessment (EA) will be prepared to evaluate the proposed amendment as well as the disposal of the tracts.

Both tracts are currently under Recreation and Public Purposes (R&PP) Act leases to Box Elder County for sanitary landfills. The intent of this action is to sell both tracts under the authority of section 203 of the Federal Land Policy and Management Act of 1976 (FLPMA) to the county for continued operation of the landfills.

Public participation is requested on the proposed amendment to identify issues of concern. For a period of 30 days from the date of this notice, interested persons may submit comments regarding the proposed amendment to: Leon E. Berggren, Bear River Resource Area Manager, Bureau of Land Management, 2370 South 2300 West, Salt Lake City, Utah 84119, Phone (801) 524-5348.

Date: November 23, 1987

Deane H. Zeller,

District Manager.

[FR Doc. 87-27808 Filed 12-3-87; 8:45 am]

BILLING CODE 4310-DQ-M

Minerals Management Service

Development Operations Coordination Document; Shell Offshore Inc.

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that Shell Offshore Inc. has submitted a DOCD describing the activities it proposes to conduct on Lease OCS-G 4126, Block 310, Main Pass Area, offshore Louisiana and Mississippi. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Venice, Louisiana.

DATE: The subject DOCD was deemed submitted on November 23, 1987.

ADDRESS: A copy of the subject DOCD is available for public review at the Public Information Office, Gulf of Mexico OCS Region, Minerals Management Service, 1201 Elmwood Park Boulevard, Room 114, New Orleans, Louisiana (Office Hours: 8 a.m. to 4:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Michael J. Tolbert, Minerals Management Service, Gulf of Mexico OCS Region, Field Operations, Plans, Platform and Pipeline Section, Exploration/Development Plans Unit; Telephone (504) 736-2867.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval for the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979 (44 FR 53685). Those practices and procedures are set out in revised § 250.34 of Title 30 of the CFR.

Date: November 24, 1987.

J. Rogers Percy,
Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 87-27837 Filed 12-3-87; 8:45 am]

BILLING CODE 4310-MR-M

INTERSTATE COMMERCE COMMISSION

Agricultural Cooperative; Intent To Perform Interstate Transportation for Certain Nonmembers

Date: December 1, 1987.

The following Notices were filed in accordance with section 10526(a)(5) of

the Interstate Commerce Act. These rules provide that agricultural cooperatives intending to perform nonmember, nonexempt, interstate transportation must file the Notice, Form BOP 102, with the Commission within 30 days of its annual meetings each year. Any subsequent change concerning officers, directors, and location of transportation records shall require the filing of a supplemental Notice within 30 days of such change.

The name and address of the agricultural cooperative (1) and (2), the location of the records (3), and the name and address of the person to whom inquiries and correspondence should be addressed (4), are published here for interested persons. Submission of information which could have bearing upon the propriety of a filing should be directed to the Commission's Office of Compliance and Consumer Assistance, Washington, DC 20423. The Notices are in a central file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Washington, DC.

(1) Agway, Inc.

(2) P.O. Box 4933, Syracuse, NY 13221

(3) P.O. Box 4933, Syracuse, NY 13221

(4) Vincent M. Spadard, Traffic Manager, P.O. Box 4853, Syracuse, NY 13221

Noreta R. McGee,

Secretary.

[FR Doc. 87-27862 Filed 12-3-87; 8:45 am]

BILLING CODE 7035-01-M

Intent To Engage in Compensated Intercompany Hauling Operations

This is to provide notice as required by 49 U.S.C. 10524(b)(1) that the named corporations intend to provide or use compensated intercompany hauling operations as authorized in 49 U.S.C. 10524(b).

A. 1. Parent corporation and address of principal office:

Tracker Marine Corporation,
Address: 1915-C South Campbell,
Springfield, Missouri 65807

2. Wholly-owned subsidiaries which will participate in the operations, and State of incorporation:

(i) Marine Transport Corporation, incorporated in the State of Missouri.

B. 1. Parent corporation and address of principal office:

West Coast Adhesives, Inc., 11104 NW.
Front Avenue, Portland, Oregon 97231

2. Wholly-owned subsidiary which will participate in the operations:

Resin Hauls, Inc., 11104 NW. Front Avenue, Portland, Oregon 97231

Resin Hauls Inc. is incorporated in: (i) Oregon

C. 1. Parent corporation address of principal office and State of Incorporation:

Sara Lee Corporation, Three First National Plaza, Chicago, Illinois 60602—Maryland

2. Wholly owned subsidiaries which will participate in the operations, the address of their respective principal offices and their States of Incorporation:

2. Aris Isotoner, Inc., 417 Fifth Avenue, New York, New York 10016—Delaware

Bali Company, 3330 Healy Dr., Winston-Salem, North Carolina 27103—Delaware

Bil Mar Foods, Inc., 8300 96th Avenue, Zeeland, Michigan 49464—Delaware

Booth Fisheries Corporation, 1300 W. Higgins, Park Ridge, Illinois 60068—Delaware

Bryan Foods, Inc., 1 Churchill Road, P.O. Box 1177, West Point, Mississippi 39773—Mississippi

Capitol Food Company, 6501 Fulton Industrial Blvd., Atlanta, Georgia 30336—Georgia

Chef Pierre, Inc., 2314 Sybrandt St., P.O. Box 1009, Traverse City, Michigan 49685—Delaware

Circle T Foods Company, Inc., 4560 Leston, Dallas, Texas 75247—Texas
Coach Leatherware Company, Inc., 516 West 34th Street, New York, New York 10001—Delaware

Country Commons Co., 500 Waukegan Road, Deerfield, Illinois 60015—Delaware

Douwe Egberts Coffee Service, Inc., 990 Supreme Drive, Bensenville, Illinois 60106—Delaware

Emmber Brand, Incorporated, P.O. Box 2006, Milwaukee, Wisconsin 53201—Wisconsin

Epic Company, Inc., Jimmy Dean Avenue, Osceola, Iowa 50213—Illinois
Frigid Freeze Foods, Inc., 1025 Electric Road, Salem, Virginia 24153—Virginia

The Fuller Brush Company, 5635 Hanes Mill Road, Winston-Salem, North Carolina 27106—Connecticut

Fuller Brush Catalog, Inc., 5635 Hanes Mill Road, Winston-Salem, North Carolina 27106—North Carolina

Gibbon Packing, Inc., P.O. Box 2006, Milwaukee, Wisconsin 53201—Connecticut

Green Hill, Inc., Rt. 11, Elliston, Virginia 24087—Virginia

Hanes Knit Products, Inc., 3334 Healy Drive, Winston-Salem, North Carolina 27103—Delaware

Hanes Menswear, Inc., 3334 Healy Drive, Winston-Salem, North Carolina 27103—Delaware

Higdon Food Service, Inc., 1350 N. 10th St., Paducah, Kentucky 40222—Kentucky

Hollywood Brands, Inc., 100 S. Poplar, Centralia, Illinois 62801—Delaware

Illinois Fruit & Produce Corp., One Quality Lane, Streator, Illinois 61364—Illinois

The Jimmy Dean Meat Company, Inc., 1341 W. Mockingbird Lane, Dallas, Texas 75247—Texas

Kitchens of Sara Lee, Inc., 500 Waukegan Road, Deerfield, Illinois 60015—Delaware

Kiwi Brands Inc., Route 662 North, Douglassville, Pennsylvania 19518—Delaware

Landlock Seafood Company, Inc., 4119 Billy Mitchell Road, Addison, Texas 75001—Texas

L'eggs Brands, Inc., P.O. Box 2495, 5660 University Parkway, Winston-Salem, North Carolina 27105—North Carolina

Lily Packing, Inc., P.O. Box 2006, Milwaukee, Wisconsin 53201—Wisconsin

Lyon's Restaurants, Inc., 1165 Triton Drive, Foster City, California 94404—Delaware

Lyon's Restaurants in Oregon, Inc., 1165 Triton Drive, Foster City, California 94404—Oregon

Moo-Battue, Inc., P.O. Box 2006, Milwaukee, Wisconsin—Wisconsin

Ozark Salad Company, Inc., 100 N. Youngman, Baxter Springs, Kansas 66713—Delaware

Peck Meat Packing Corporation, P.O. Box 2006, Milwaukee, Wisconsin 53201—Wisconsin

Priddy's Quality Foods, Inc., 204 H. N.E., Ardmore, Oklahoma 73401—Oklahoma

PYA/Monarch, Inc., 107 Frederick Street, P.O. Box 1328, Greenville, South Carolina 29602—Delaware

Rice Hosiery Corporation, 550 Fairfield Road, High Point, North Carolina—North Carolina

Schloss & Kahn, Inc., US Highway 80 & Newcomb Avenue, Montgomery, Alabama 36195—Delaware

Seitz Foods, Inc., Box 247, St. Joseph, Missouri 64502—Delaware

Sky Bros., Inc., Burns Avenue at Canan Station, Altoona, Pennsylvania 16603—Pennsylvania

Standard Meat Company, 3709 East First Street, Fort Worth, Texas 76111—Texas

Superior Coffee and Foods, Inc., 990 Supreme Drive, Bensenville, Illinois 60106—Illinois

Twin Rivers Transportation Company, 955 Hamilton Drive, University Park, Illinois 60466—Illinois

Wolferman's Inc., One Muffin Lane, North Kansas City, Missouri 64116—Delaware

3. Wholly owned divisions which will participate in the operations and their addresses:

Buring Foods, division of Sara Lee Corporation, 1837 Harbor Ave., Memphis, Tennessee 38113

Direct Marketing, division of Sara Lee Corporation, 480 Hanes Mill Road, Winston-Salem, North Carolina 27105

Direct Sales, division of Sara Lee Corporation, 470 Hanes Mill Road, Winston-Salem, North Carolina 27105

Direct Store Delivery, division of Sara Lee Corporation, 5650 University Parkway, Winston-Salem, North Carolina 27106

Gallileo-Capri Salami, division of Sara Lee Corporation, 2411 Baumann Ave., San Lorenzo, California 94580

Gallo Salame, division of Sara Lee Corporation, 250 Brannan St., San Francisco, California 94107

Gordon County Farm Company, division of Rudy's Farm Company, P.O. Box 1267, Mauldin Road, Calhoun, Georgia 30701

Hanes Hosiery, division of Sara Lee Corporation, 401 Hanes Mill Road, Winston-Salem, North Carolina 27105

Hanes Knitwear, division of Hanes Knit Products, Inc., 450 Hanes Mill Road, Winston-Salem, North Carolina 27105

Hanes Printables, division of Hanes Knit Products, Inc., 3334 Healy Drive, Winston-Salem, North Carolina 27103

Hi-Brand Foods, division of Sara Lee Corporation, P.O. Box 2048, Peachtree City, Georgia 30269

Hillshire Farm Company, division of Sara Lee Corporation, P.O. Box 227, Rte. No. 4, New London, Wisconsin 54961

Kahn's and Company, division of Sara Lee Corporation, 3241 Spring Grove Ave., Cincinnati, Ohio 45225

Karico, division of Superior Coffee and Food division, 990 Supreme Drive, Bensenville, Illinois 60106

L'eggs Products, division of Sara Lee Corporation, P.O. Box 2495, 5660 University Parkway, Winston-Salem, North Carolina 27105

R.B. Rice Company, division of Sara Lee Corporation, 1951 Rice Road, Lee's Summit, Missouri 64063

Rudy's Farm Company, division of Sara Lee Corporation, 2424 Music Valley Drive, Nashville, Tennessee 37214

Superior Coffee and Foods, division of Sara Lee Corporation, 990 Supreme Drive, Bensenville, Illinois 60106

Sweet Sue Kitchens, division of Sara Lee Corporation, McArthur Drive, Athens, Alabama 35611

Noreta R. McGee,

Secretary.

[FR Doc. 87-27863 Filed 12-3-87; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 31163]

Winona Bridge Railway Co.—Trackage Rights—Burlington Northern Railroad Co.

Burlington Northern Railroad Company (BN) has agreed to grant overhead track rights to its wholly-owned subsidiary, Winona Bridge Railway Company (WB), between Winona Junction, WI, and Seattle, WA, a distance of approximately 1,860 miles. The rights granted to WB restrict it from serving and/or switching industries located along the BN trackage, except that WB shall have the right to pick up and set out traffic at BN's TOFC/COFC hub centers in St. Paul, MN, and Spokane and Seattle, WA. The BN-WB trackage rights transaction was entered into on November 16, 1987, and became effective on November 25, 1987.

This notice is filed under 49 CFR 1180.2(d)(7). Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction.

As a condition to use of this exemption, any employees affected by the trackage rights will be protected pursuant to *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

Dated: November 25, 1987.

By the Commission, Jane F. Mackall,
Director, Office of Proceedings.

Noreta R. McGee,

Secretary.

[FR Doc. 87-27773 Filed 12-3-87; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research Act of 1984; Corporation for Open Systems International

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 *et seq.* ("the Act"), the Corporation for Open Systems International ("COS") has filed an additional written notification simultaneously with the Attorney General and the Federal Trade Commission on October 23, 1987, disclosing a joint development agreement between COS and the National Computing Centre Limited of Manchester, England. The additional

written notification was filed for the purpose of extending the protections of section 4 of the Act limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

On May 14, 1986, COS filed its original notification pursuant to section 6(a) of the Act. The Department of Justice (the "Department") published a notice in the *Federal Register* pursuant to section 6(b) of the Act on June 11, 1986, 51 FR 21260. On August 6, 1986, September 30, 1986, January 2, 1987, March 24, 1987, June 12, 1987, July 18, 1987, July 24, 1987, and October 5, 1987, COS filed additional written notifications. The Department published notices in the *Federal Register* in response to these additional notifications on September 4, 1986 (51 FR 31735), October 28, 1986 (51 FR 39434), February 13, 1987 (52 FR 4671), April 24, 1987 (52 FR 13769), July 21, 1987 (52 FR 27473), October 7, 1987 (52 FR 37539), and November 9, 1987 (52 FR 43138), respectively.

On September 15, 1987, the Corporation for Open Systems International entered into a written joint development agreement with the National Computing Centre Limited, a United Kingdom company, the purpose of which is to jointly develop a Message Handling Test System.

Joseph H. Widmar,
Director of Operations, Antitrust Division.

[FR Doc. 87-27844 Filed 12-3-87; 8:45 am]

BILLING CODE 4410-01-M

Drug Enforcement Administration

Manufacturer of Controlled Substances; Registration

By Notice dated July 22, 1987, and published in the *Federal Register* on July 28, 1987; (52 FR 28201), Arenol Chemical Corporation of New Jersey, a new applicant, 40-33 23rd Street, Long Island City, New York 11101, made application to the Drug Enforcement Administration to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Amphetamine, its salts, optical isomers, and salts of its optical isomers (1100).	II
Methamphetamine, its salts, isomers, and salts of its isomers (1105).	II

No comments or objections have been received. Therefore, pursuant to section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and Title 21, Code of Federal Regulations, § 1301.54(e), the Deputy Assistant Administrator hereby orders that the application submitted by the above firm

for registration as a bulk manufacturer of the basic classes of controlled substances listed above is granted.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

Dated: November 30, 1987.

[FR Doc. 87-27869 Filed 12-3-87; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 87-1]

Hearing; Lewis K. Curtwright, D.O., Milford, OH

Notice is hereby given that on December 6, 1986, the Drug Enforcement Administration, Department of Justice, issued to Lewis K. Curtwright, D.O., an Order to Show Cause as to why the Drug Enforcement Administration should not revoke your DEA Certificate of Registration, BC0306399, and deny any pending applications for renewal.

Thirty days having elapsed since the said Order to Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held commencing at 10:00 a.m. on Thursday, December 3, 1987, in Courtroom No. 10, United States Claims Court, 717 Madison Place NW., Washington, DC.

Dated: December 1, 1987.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 87-27870 Filed 12-3-87; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-20.074]

The Gleason Works Rochester, NY; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on October 28, 1987 applicable to all workers of The Gleason Works, Rochester, New York. The Certification was published in the *Federal Register* on November 10, 1987 (52 FR 43258).

Based on new information furnished by the company, the Office of Trade Adjustment Assistance, reviewed the

certification. The additional information from the company revealed a separate worker group (Cutter Division) which had decreased sales and production and employment declines in 1987 at The Gleason Works and increased company imports. Company officials indicated that cutter production is in the final stages of being moved to England.

The intent of the certification is to cover all workers of The Gleason Works, Rochester, New York who were affected by increased imports of cutters and machine tools for gears. The amended notice applicable to TA-W-20,074 is hereby issued as follows:

All workers of The Gleason Works, Rochester, New York who became totally or partially separated from employment on or after August 29, 1986 and before January 15, 1987 and all workers of the Cutter Division of The Gleason Works, Rochester, New York who became totally or partially separated from employment on or after January 15, 1987 are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.

Signed at Washington, DC, this 25 day of November, 1987

Harold A. Bratt,

Deputy Director, Office of Program Management, UIS.

[FR Doc. 87-27962 Filed 12-3-87; 8:45 am]

BILLING CODE 4510-30-M

Federal-State Unemployment Compensation Program; Certification Relating to Reduced Credits Under the Federal Unemployment Tax Act for 1987

Section 3302(c)(2) of the Federal Unemployment Tax Act (FUTA) provides for the repayment, through reduced credits, of outstanding balances of repayable advances made to States under Title XII of the Social Security Act. States that meet specific criteria under subsections (c), (f), or (g) of section 3302 may have the credit reduction limited or not applied. The certification to the Secretary of the Treasury of States subject to the credit reduction for 1987 and States that qualify for credit reduction relief is published below.

Date: November 30, 1987.

Roger D. Semerad,

Assistant Secretary of Labor.

November 10, 1987.

The Honorable James A. Baker III,
Secretary of the Treasury, Washington, DC

Dear Secretary Baker: This is to verify the States which have an outstanding balance of repayable advances under Title XII of the Social Security Act and to notify you of my determination as to the status of the States

with regard to the reduction in credit provisions of Section 3302(c)(2) of the Federal Unemployment Tax Act (FUTA).

Pursuant to delegation of authority to me, I have determined that employers in two States are subject to a reduction in FUTA offset credit for taxable year 1987:

Michigan
Pennsylvania

Under certain conditions, subsection (f) of Section 3302 of the FUTA limits or caps the FUTA tax credit reduction in a year to an amount which does not exceed the greater of 0.6 percent of wages subject to FUTA or the percentage reduction that was in effect for the preceding taxable year. To qualify for a cap in taxable year 1987, the Secretary of Labor (or his delegate) must determine that a State has taken no action in the 12 months ending on September 30, 1987, unless required under State law in effect before August 13, 1981, which has resulted or will result in:

(1) a reduction in the State's unemployment tax effort, or

(2) a net decrease in the solvency of the State unemployment compensation system, and, further, that:

(3) the State unemployment tax rate for the calendar year equals or exceeds the average benefit cost ratio for calendar years in the five-calendar year period ending with calendar year 1986, and

(4) the outstanding balance of advances to the State on September 30 of calendar year 1987 was not greater than the outstanding balance for such State on September 30, 1984.

Pursuant to delegation of authority to me, I have determined that under criteria one State (Michigan) qualifies for the cap, but is not subject to reduced FUTA credits for 1987 because it also qualifies for avoidance of the offset credit reduction under subsection (g) of Section 3302 as noted below.

I have also determined that one State is not affected by the cap and is subject to reduced FUTA credits for 1987 as follows:

Pennsylvania 1.5%

Subsection (g) of Section 3302 gives a State the option of repaying on or before November 9 a portion of its outstanding loans each year through transfer of a specified amount from its account in the Unemployment Trust Fund (UTF) to the Federal Unemployment Account (FUA) in the UTF. The transfer to FUA would be in lieu of a reduced credit in the Federal tax paid by the employers in the State. The State must meet, as determined by the Secretary of Labor (or his delegate), the following criteria in order to avoid the offset credit reduction for 1987:

(1) make repayments to FUA during the one-year period ending on November 9, 1987, of an amount not less than the sum of all loans made to the State in the one-year period ending on such November 9, plus the potential additional taxes due by reason of the reduced credit applicable to taxable year 1987;

(2) have or will have sufficient funds remaining after such repayments to pay benefits for at least three months from November 1 of the same year without receiving another Title XII advance; and

(3) have taken action by amendment of the State law, after the date of the first advance is taken into account, to increase the net solvency of its UI system, and such net increase equals or exceeds the potential additional taxes for such taxable year.

Pursuant to delegation of authority to me, I have determined that under these criteria one State qualifies and is thus not subject to reduced FUTA credits for 1987 as follows:

Michigan

Further, I have determined that the State of Texas has an outstanding balance of Title XII advances as of November 10, 1987, but is not subject to reduced credits for 1987.

Sincerely,

Carolyn M. Golding,

Director, Unemployment Insurance Service.

[FR Doc. 87-27903 Filed 12-3-87; 8:45 am]

BILLING CODE 4510-30-M

Federal-State Unemployment Compensation Program; Certification of Interest Relief: Certification of States Qualifying For Partial Relief of Interest Due on Advances Under Title XII of the Social Security Act For 1987

Title XII of the Social Security Act provides for deferral and delay of interest payable by States on advances received by them from the Federal unemployment account in the Unemployment Trust Fund if the States meet criteria set forth in the statute. The certification to the Secretary of the Treasury of specified States that meet the respective criteria with respect to interest due prior to October 1, 1987, is published below.

Date: November 30, 1987.

Roger D. Semerad,
Assistant Secretary of Labor.

September 10, 1987.

The Honorable James A. Baker III,
Secretary of the Treasury, Washington, DC 20220.

Dear Secretary Baker: The Department of Labor has reviewed States' applications for relief from interest payments which are due prior to October 1, 1987. The interest relief options available to States are:

(1) *High Unemployment Deferral:* Section 1202(b)(3)(C) of the Social Security Act (SSA) allows a State to defer 75 percent of interest otherwise due if the rate of insured unemployment under the State law for the period consisting of the first six months of the preceding calendar year equaled or exceeded 7.5 percent. The State must pay 75 percent of interest otherwise due in three annual installments of at least 25 percent beginning with the year after the year in which it was due. The interest deferred does not accrue interest.

(2) *High Unemployment Delay of Payment Due:* Section 1202(b)(9) of the SSA allows a

State to delay up to nine months the payment of interest due September 30 of any calendar year after 1982 during which the average total unemployment rate (TUR) in the State was 13.5 percent TUR or higher for the most recent 12-month period for which data are available. The State must meet the 13.5 percent requirement each succeeding year in order to delay payments nine months in such succeeding years.

There were no States which qualified for the above relief.

The following States have qualified for deferral of interest in previous years, have taken no action to reduce solvency, and thus meet the requirements to continue the installment payment of interest: Colorado, Kentucky, Illinois, Michigan, Ohio, Pennsylvania, West Virginia, and Wisconsin.

Sincerely,

Robert Deslongchamps,

for Carolyn M. Golding,

Director, Unemployment Insurance Service.

[FR Doc. 87-27904 Filed 12-3-87; 8:45 am]

BILLING CODE 4510-30-M

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR Part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR Part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in

accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedeas decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts," shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S-3504, Washington, DC 20210.

Modifications to General Wage Determination Decisions

The numbers of the decisions listed in the Government Printing Office document entitled "General Wage

Determinations Issued Under the Davis-Bacon and Related Acts" being modified are listed by Volume, State, and page number(s). Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

District of Columbia: DC87-1 (Jan. 2, 1987) .. p. 86.
Florida: FL87-1 (Jan. 2, 1987) pp. 110-112.
Massachusetts: MA87-3 (Jan. 2, 1987) pp. 402-405.
New York: NY87-9 (Jan. 2, 1987) p. 768.
New York: NY87-10 (Jan. 2, 1987) p. 771.
New York: NY87-15 (Jan. 2, 1987) p. 812.
Pennsylvania: PA87-5 (Jan. 2, 1987) p. 883.
Tennessee: TN87-5 (Jan. 2, 1987) pp. 1096-1098.

Volume II

Illinois: IL87-15 (Jan. 2, 1987) pp. 197-204.
Ohio: OH87-2 (Jan. 2, 1987) p. 736.
Ohio: OH87-29 (Jan. 2, 1987) p. 822.

Volume III

Arizona: AZ87-3 (Jan. 2, 1987) pp. 30-33.

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts". This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the County. Subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 783-3238.

When ordering subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the three separate volumes, arranged by State. Subscriptions include an annual edition (issued on or about January 1) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC this 27th day of November 1987.

Alan L. Moss,
Director, Division of Wage Determinations.

[FR Doc. 87-27633 Filed 12-3-87; 8:45 am]

BILLING CODE 4510-27-M

Mine Safety and Health Administration

[Docket No. M-87-32-M]

Big Horn Redi-Mix, Inc.; Petition for Modification of Application of Mandatory Safety Standard

Big Horn Redi-Mix, Inc., P.O. Box 672, Greybull, Wyoming 82426 has filed a petition to modify the application of 30 CFR 56.12028 (testing grounding systems) to its Big Horn Mine (I.D. No. 48-00266) located in Big Horn County, Wyoming. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that continuity and resistance grounding systems be tested immediately after installation, repair, and modification, and annually thereafter.

2. Petitioner requests a modification of the standard as it pertains to the testing of the resistance of the grounding electrodes where the portable plants relocate.

3. In support of this request, petitioner states that—

(a) When a grounding electrode system is made, one or more of the electrodes specified below will be used. Made electrodes will be imbedded below the permanent moisture level;

(b) Made electrodes will be free from nonconductive coatings such as paint or enamel;

(c) Where more than one electrode system is used (including those used for lightning rods), each electrode of one system will not be less than 6 feet from the other electrode of another system;

(d) Rod and pipe electrodes will not be less than 8 feet in length;

(e) Electrodes of pipe or conduit will not be smaller than ¾ inch trade size and, where of iron or steel, shall have the outer surface galvanized or otherwise metal-coated for corrosion protection;

(f) Electrodes of rods of steel or iron shall be at least ¾ inch diameter. Nonferrous rods or their equivalent will not be less than ½ inch in diameter;

(g) Where rock bottom is not encountered, the electrodes will be driven to a depth of 8 feet. Where rock bottom is encountered at a depth of less than 8 feet, electrodes not less than 8 feet long will be buried in a trench;

(h) The ground rods and associated bonds will be visually inspected for physical deterioration and mechanical

bonding each time a portable operation is relocated;

(i) Annual ground bed measurements will be performed at the site where any portable plant remains in the same location for more than one calendar year; and

(j) The grounding conductor is most susceptible to breaking due to flexing and disconnecting/reconnecting during these moves. Therefore, equipment grounding conductor continuity measurements will be performed after each relocation of a portable plant.

4. For these reasons, petitioner requests a modification of the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before January 4, 1988. Copies of the petition are available for inspection at that address.

Patricia W. Silvey,

Acting Associate Assistant Secretary for Mine Safety and Health.

Date: November 20, 1987.

[FR Doc. 87-27892 Filed 12-3-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket NO. M-87-225-C]

Chestnut Coal Co.; Petition for Modification of Application of Mandatory Safety Standard

Chestnut Coal Company, R.D. 3, Box 142-B, Sunbury, Pennsylvania 17801 has filed a petition to modify the application of 30 CFR 75.1400 (hoisting equipment; general) to its No. 10 Slope (I.D. NO. 38-07059) located in Northumberland County, Pennsylvania. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that cages, platforms or other devices which are used to transport persons in shafts and slopes be equipped with safety catches or other approved devices that act quickly and effectively in an emergency.

2. Petitioner states that no such safety catch or device is available for the steeply pitching and undulating slopes with numerous curves and knuckles present in the main haulage slopes of this anthracite mine.

3. Petitioner further believes that if "makeshift" safety devices were installed they would be activated on knuckles and curves when no emergency existed and cause a tumbling effect on the conveyance.

4. As an alternate method, petitioner proposes to operate the man cage or steel gunboat with secondary safety connections securely fastened around the gunboat and to the hoisting rope, above the main connecting device. The hoisting ropes would have a factor of safety in excess of the design factor as determined by the formula specified in the American National Standard for Wire Rope for Mines.

5. Petitioner states that the proposed alternate method will provide the same degree of safety for the miners affected as that afforded by the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before January 4, 1988. Copies of the petition are available for inspection at that address.

Patricia W. Silvey,

Acting Associate Assistant Secretary for Mine Safety and Health.

Dated: November 20, 1987.

[FR Doc. 87-27893 Filed 12-3-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-86-167-C]

Clinchfield Coal Co.; Petition for Modification of Application of Mandatory Safety Standard (Amendment)

Clinchfield Coal Company, P.O. Box 7, Dante, Virginia 24237 has filed an amendment to a petition for modification. On August 22, 1986, Clinchfield Coal Company, submitted a petition to modify the application of 30 CFR 75.326 (aircourses and belt haulage entries) to its McClure No. 1 Mine (I.D. No. 44-04251) located in Russell County, Virginia. On November 25, 1986, MSHA published notice of this petition in the *Federal Register* (51 FR 42663), allowing interested parties 30 days to submit comments. On February 10, 1987, a proposed decision and order was issued granting this petition with special terms and conditions. On July 13, 1987, petitioner submitted a request to amend paragraph 1(d) of the proposed decision

and order. Paragraph 1(d) is hereby amended to read: The velocity of air in the belt conveyor will be 50 feet a minute, or greater, and have a definite and distinct movement in the designated direction, in order to comply with the requirements of this petition. The velocity of air current in the belt conveyor entry will not exceed 1200 feet per minute. The amendment is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

Request for Comments

Persons interested in this amendment to the petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before January 4, 1988. Copies of the amendment and the original petition for modification are available for inspection at that address.

Patricia W. Silvey,

Acting Associate Assistant Secretary for Mine Safety and Health.

Date: November 18, 1987.

[FR Doc. 87-27897 Filed 12-3-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-86-168-C]

Clinchfield Coal Co.; Petition for Modification of Application of Mandatory Safety Standard (Amendment)

Clinchfield Coal Company, P.O. Box 7, Dante, Virginia 24237 has filed an amendment to a petition for modification. On August 22, 1986, Clinchfield Coal Company, submitted a petition to modify the application of 30 CFR 75.326 (aircourses and belt haulage entries) to its Splashdam Mine (I.D. NO. 44-00269) located in Dickenson County, Virginia. On December 9, 1986, MSHA published notice of this petition in the *Federal Register* (51 FR 44388), allowing interested parties 30 days to submit comments. On May 19, 1987, a proposed decision and order was issued granting this petition with special terms and conditions. On September 14, 1987, petitioner submitted a request to amend paragraph 1(d) of the proposed decision and order. Paragraph 1(d) is hereby amended to read: The velocity of air in the belt conveyor will be 50 feet a minute, or greater, and have a definite and distinct movement in the designated direction, in order to comply with the requirements of this petition. The

velocity of air current in the belt conveyor entry will not exceed 1200 feet per minute. The amendment is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

Request for Comments

Persons interested in this amendment to the petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before January 4, 1988. Copies of the amendment and the original petition for modification are available for inspection at that address.

Patricia W. Silvey,

Acting Associate Assistant Secretary for Mine Safety and Health.

Date: November 23, 1987.

[FR Doc. 87-27898 Filed 12-3-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-86-169-C]

Clinchfield Coal Co.; Petition for Modification of Application of Mandatory Safety Standard (Amendment)

Clinchfield Coal Company, P.O. Box 7, Dante, Virginia 24237 has filed an amendment to a petition for modification. On August 22, 1986, Clinchfield Coal Company, submitted a petition to modify the application of 30 CFR 75.1103-4(a) (automatic fire sensor and warning device systems; installation; minimum requirements) to its Splashdam Mine (I.D. No. 44-00269) located in Dickenson County, Virginia. On December 9, 1986, MSHA published notice of this petition in the *Federal Register* (51 FR 44389), allowing interested parties 30 days to submit comments. On May 19, 1987, a proposed decision and order was issued granting this petition with special terms and conditions. On September 14, 1987, petitioner submitted a request to amend paragraph 1(d) of the proposed decision and order. Paragraph 1(d) is hereby amended to read: The velocity of air in the belt conveyor will be 50 feet a minute, or greater, and have a definite and distinct movement in the designated direction, in order to comply with the requirements of this petition. The velocity of air current in the belt conveyor entry will not exceed 1200 feet per minute. The amendment is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

Request for Comments

Persons interested in this amendment to the petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before January 4, 1988. Copies of the amendment and the original petition for modification are available for inspection at the address.

Patricia W. Silvey,

Acting Associate Assistant Secretary for Mine Safety and Health.

Date: November 23, 1987.

[FR Doc. 87-27899 Filed 12-3-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-86-170-C]

Clinchfield Coal Co.; Petition for Modification of Application of Mandatory Safety Standard (Amendment)

Clinchfield Coal Company, P.O. Box 7, Dante, Virginia 24237 has filed an amendment to a petition for modification. On August 22, 1986, Clinchfield Coal Company, submitted a petition to modify the application of 30 CFR 75.1105 (housing of underground transformer stations, battery-charging stations, substations, compressor stations, shops, and permanent pumps) to its Splashdam Mine (I.D. No. 44-00269) located in Dickenson County, Virginia. On December 9, 1986, MSHA published notice of this petition in the *Federal Register* (51 FR 44389), allowing interested parties 30 days to submit comments. On May 19, 1987, a proposed decision and order was issued granting this petition with special terms and conditions. On September 14, 1987, petitioner submitted a request to amend paragraph 1(d) of the proposed decision and order. Paragraph 1(d) is hereby amended to read: The velocity of air in the belt conveyor will be 50 feet a minute, or greater, and have a definite and distinct movement in the designated direction, in order to comply with the requirements of this petition. The velocity of air current in the belt conveyor entry will not exceed 1200 feet per minute. The amendment is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

Request for Comments

Persons interested in this amendment to the petition may furnish written comments. These comments must be filed with the Office of Standards,

Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before (January 4, 1988. Copies of the amendment and the original petition for modification are available for inspection at that address.

Patricia W. Silvey,

Acting Associate Assistant Secretary for Mine Safety and Health.

Date: November 23, 1987.

[FR Doc. 87-27900 Filed 12-3-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-85-184-C]

Clinchfield Coal Co.; Petition for Modification of Application of Mandatory Safety Standard (Amendment)

Clinchfield Coal Company, P.O. Box 7, Dante, Virginia 24237 has filed an amendment to a petition for modification. On November 1, 1985, Clinchfield Coal Company, submitted a petition to modify the application of 30 CFR 75.1105 (housing of underground transfer stations, battery-charging stations, substations, compressor stations, shops, and permanent pumps) to its McClure No. 1 Mine (I.D. No. 44-04251) located in Dickenson County, Virginia. On January 14, 1986, MSHA published notice of this petition in the *Federal Register* (51 FR 1585), allowing interested parties 30 days to submit comments. On February 10, 1987, a proposed decision and order was issued granting this petition with special terms and conditions. On September 14, 1987, petitioner submitted a request to amend paragraph 1(d) of the proposed decision and order. Paragraph 1(d) is hereby amended to read: the velocity of air in the belt conveyor will be 50 feet a minute, or greater, and have a definite and distinct movement in the designated direction, in order to comply with the requirements of this petition. The velocity of air current in the belt conveyor entry will not exceed 1200 feet per minute. The amendment is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

Request for Comments

Persons interested in this amendment to the petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be

postmarked or received in that office on or before January 4, 1988. Copies of the amendment and the original petition for modification are available for inspection at that address.

Patricia W. Silvey,

Acting Association Assistant Secretary for Mine Safety and Health.

Date: November 23, 1987.

[FR Doc. 87-27901 Filed 12-3-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-87-221-C]

Production Coal Co., Inc.; Petition for Modification of Application of Mandatory Safety Standard

Production Coal Company, Inc., P.O. Box 1257 Main Street Station, Pikeville, Kentucky 41501 has filed a petition to modify the application of 30 CFR 75.1719 (illumination) to its Jehovah Mine (I.D. No. 15-15901) located in Floyd County, Kentucky. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that all working places in a mine be illuminated by permissible lighting while persons are working in such places.
2. The mine is 34 to 37 inches in height with unlevel bottom, and there is only six inches between the frame of the equipment and the roof.
3. Petitioner states that the use of space lights would result in a diminution of safety to the miners affected because they have a blinding effect, which could impair equipment operator's vision, when tramming and could result in electrical shock if a cable is out.
4. Petitioner further states that there are two headlights and two rear headlights on all underground equipment, which provides adequate light for the miners to tram with.
5. For these reasons, petitioner requests a modification of the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before January 4, 1988. Copies of the petition

are available for inspection at that address.

Patricia W. Silvey,

Acting Associate Assistant Secretary for Mine Safety and Health.

Date: November 20, 1987.

[FR Doc. 87-27894 Filed 12-3-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-87-220-C]

R.S. & W. Coal Co.; Petition for Modification of Application of Mandatory Safety Standard

R.S. & W. Coal Company, Box 36, Klingerstown, Pennsylvania 17941 has filed a petition to modify the application of 30 CFR 75.1405 (automatic couplers) to its R.S. & W. Drift Mine (I.D. No. 36-01818) located in Schuylkill County, Pennsylvania. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that track haulage cars be equipped with automatic couplers.
2. Petitioner states that installation of automatic couplers on the track haulage cars would result in a diminution of safety to the miners affected due to the sharp radius curves in the track, the undulating pitch of the slopes, the different types of small lightweight cars, and the systems of haulage.
3. For these reasons, petitioner requests a modification of the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before January 4, 1988. Copies of the petition are available for inspection at that address.

Patricia W. Silvey,

Acting Associate Assistant Secretary for Mine Safety and Health.

Date: November 20, 1987.

[FR Doc. 87-27895 Filed 12-3-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-87-211-C]

South East Coal Co.; Petition for Modification of Application of Mandatory Safety Standard

South East Coal Company, P.O. Box 219, Isom, Kentucky 41824 has filed a

petition to modify the application of 30 CFR 75.1710 (cabs and canopies) to its Mine No. 403 (I.D. No. 15-05427) Located in Knott County, Kentucky. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that cabs or canopies be installed on the mine's electric face equipment.
2. Petitioner states that the use of cabs or canopies on the mine's electric face equipment would result in a diminution of safety to the miners affected because the cabs or canopies would shear off roof bolts and create unsupported top. The cabs or canopies would also impair the equipment operator's visibility, and create cramped conditions causing fatigue resulting in reduced alertness and safety.
3. For these reasons, petitioner requests a modification of the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before January 4, 1988. Copies of the petition are available for inspection at the address.

Patricia W. Silvey,

Acting Associate Assistant Secretary for Mine Safety and Health.

Date: November 20, 1987.

[FR Doc. 87-27896 Filed 12-3-87; 8:45 am]

BILLING CODE 4510-43-M

NUCLEAR REGULATORY COMMISSION

Nuclear Power Plant Aging Symposium; Meeting

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Meeting.

SUMMARY: The study of nuclear power plant aging is part of the NRC's current research program to improve the safety of nuclear power plants. The nuclear community in the United States has entered a period during which issues related to the advancing age of nuclear power plants will play an ever increasing role in the decisionmaking process for the continued safe operation

of these plants. Although progress has been made in understanding and managing aging phenomena, NRC believes that much remains to be done. The theme of this international Symposium is: "Understanding Aging—A Key to Ensuring Safety; Managing Aging—A Necessity to Ensuring Safety."

The Symposium is being organized by NRC in cooperation with the American Nuclear Society, the American Society of Civil Engineers, the American Society of Mechanical Engineers, and the Institute of Electrical and Electronics Engineers. Technical papers on the general theme of the Symposium are invited.

DATE: August 30, 31 and September 1, 1988.

ADDRESS: Hyatt Regency, One Bethesda Metro Center, Bethesda, Maryland 20814.

ADMISSION: Prior registration is required. Only first 500 registrants are assured participation.

FOR FURTHER INFORMATION CONTACT: Mr. Satish K. Aggarwal, General Chairman, Nuclear Power Plant Aging Symposium, U.S. Nuclear Regulatory Commission, Washington, DC 20555 Phone: 301-492-3823.

Dated at Rockville, Maryland, this 30th day of November 1987.

For the Nuclear Regulatory Commission,
Guy A. Arlotto,

Director, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 87-27881 Filed 12-3-87; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-416]

Mississippi Power & Light Co. et al.; Consideration of Issuance of Amendment to Facility Operating License and Proposed No Significant Hazards; Consideration Determination and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF-29 issued to Mississippi Power & Light Company, System Energy Resources, Inc., and South Mississippi Electric Power Association for operation of the Grand Gulf Nuclear Station, Unit 1, located in Claiborne County, Mississippi.

The proposed amendment would provide interim changes to the Technical Specifications (TS) for the standby liquid control system (SLCS) and the ATWS recirculation pump trip (ATWS-RPT) system to reflect modifications to these systems. The modifications to

these systems will be made during the second refueling outage to conform to 10 CFR 50.62 regarding anticipated transients without scram (ATWS). A third system required by 10 CFR 50.62, the alternate rod insertion (ARI) system, which will be installed during the second refueling outage, will not require changes to the TS at this time. The staff will provide guidance on a generic basis regarding TS requirements for the ATWS-RPT and ARI systems at a later date.

The following changes to Grand Gulf Nuclear Station, Unit 1, will be made during the second refueling outage to implement 10 CFR 50.62:

(a) The ATWS-RPT will be modified by:

- (1) Adding a redundant trip feature.
- (2) Making the trip logic two-out-of-two for reactor pressure vessel (RPV) pressure or level and energized to trip.
- (3) Revising the RPV pressure high trip setpoint to bound less severe transients initiated at less than rated power.

(b) Installation of the ARI system will include:

- (1) Making three parallel vent paths from the scram pilot air header consisting of two valves per vent path.
- (2) Utilizing the same trip system as ATWS-RPT with the same trip logic to actuate the ARI system valves.
- (c) SLCS modifications will include:
 - (1) Utilizing simultaneous operation of both existing SLCS pumps to achieve a minimum injection rate of 82.4 gpm.
 - (2) Increasing the sodium pentaborate concentration to greater than or equal to 13.6% by weight.
 - (3) Increasing the SLCS pump discharge pressure from 1220 to 1300 psig for surveillance tests to demonstrate SLCS pump flow.
 - (4) Restricting SLCS storage tank temperature to no greater than 130° F.
 - (5) Modifying the discharge piping to inject sodium pentaborate into the high pressure core spray system instead of into the reactor vessel and adding pulsation dampeners at the pump discharge.

(6) Increasing SLCS design pressure and relief valve setpoint to 1500 psig.

The modifications to the ATWS-RPT and the SLCS are reflected in proposed Technical Specification changes as follows:

(a) For TS 3/4.3.4.1, "ATWS-RPT System Instrumentation":

- (1) Three action statements would be added to state requirements when instrumentation is inoperable.
- (2) The trip setpoint and allowable value for the reactor vessel high pressure signal would be decreased.

(3) The TS bases would be revised to reflect the ATWS-RPT system modifications.

(b) For TS 3/4.1.5, "Standby Liquid Control System":

(1) Surveillance requirements would be changed to reflect the new sodium pentaborate solution requirements.

(2) The pump discharge pressure would be increased from 1220 to 1300 psig for the SLCS pump surveillance test.

(3) The SLCS pump relief valve setting would be increased from 1400 psig to 1500 psig to reflect the higher system design pressure.

(4) The TS bases would be revised to reflect the SLCS system modifications.

(c) For TS 3/4.6.4, "Containment and Drywell Isolation Valves":

(1) The list of drywell isolation valves would be changed to reflect the modified SLCS discharge piping.

System Energy Resources, Inc. (SERI or the licensee) requested the above changes to the TS in an application for amendment, dated August 13, 1987, as revised October 23, 1987 and November 25, 1987.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

By letter dated November 25, 1987, the licensee provided its analysis about the issue of no significant hazards consideration. The licensee's analysis is included below:

1. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

a. The probability of an ATWS event occurring does not increase due to these changes since they are of a mitigative nature and do not affect the ATWS event precursors. These changes do not involve a significant increase in the consequences of an accident previously evaluated. The ATWS-RPT system provides a fully redundant trip of the recirculation pump motors including the low frequency motor generator set so that the

pumps coast down to zero speed. This trip function reduces core flow creating steam voids in the core, thereby decreasing power generation and limiting any power or pressure excursions.

b. The ARI system that will be installed during the second refueling outage is described in letters to the NRC dated October 14, 1985, April 3, 1987 and August 13, 1987. The ARI system uses the same setpoints and trip channels (transmitters and trip units) as the RPT system. Both the ARI and RPT systems are designed to perform a mitigative function during an ATWS event. The probability of an ATWS event occurring does not increase due to the commonality of the ARI and RPT trip channel since these systems perform a mitigative function and do not affect the ATWS event precursors.

Both the ATWS topical report NEDE-31096-P and the NRC Staff's safety evaluation associated with the report endorse the use of existing RPT instrumentation where possible for the ARI system. The consequences of an ATWS event are not significantly increased by connecting the ARI valves to the RPT trip circuits. The ARI system has been designed to minimize the possibility of an inadvertent trip action by use of series vent valves, energized to trip solenoids and required two out of two logic.

c. The operation of the two SLCS pumps in conjunction with the increased sodium pentaborate weight percent concentration merely provides a backup to other safety-related systems in accordance with the requirements of 10 CFR 50.62.

This rerouted SLCS discharge piping inside the drywell will provide more effective boron mixing in the reactor vessel. The piping will be constructed to ASME Section III Class 1 and Seismic Category I requirements and therefore will not increase the consequences of a LOCA or Seismic event. The relocated low point drain inside the drywell will be isolated from the containment by two normally closed isolation valves and, therefore, will not create a new leakage path to the containment. Movement of the ASME Class 1 boundary from the F004 (A and B) valves to the F006 [valve] will not increase the probability or consequences of an accident because the reactor coolant system will still be isolated from other Class 2 components by two normally closed ASME Class 1 valves.

The proposed increase in the SLCS pump relief valve setpoint is within ASME Code allowables and will not increase the probability of piping failure. The consequences of previously evaluated accidents remain unchanged since the relief valve will still perform its intended function of preventing the SLCS discharge piping from exceeding its design pressure.

Based upon the above, the probability or consequences of an accident will not be significantly increased.

2. The proposed amendment does not create the possibility of a new or different kind of accident from any previously analyzed.

a. The ATWS changes proposed and the accompanying plant modifications only serve as backups to already existing safety-related systems. The proposed changes will ensure

that the ATWS-RPT and SLCS systems are maintained such that they are capable of fulfilling the operability requirements of 10 CFR 50.62.

b. The ARI system is being installed to help mitigate the consequences of an ATWS event. As discussed above, the ARI system is designed to minimize the possibility of inadvertent trips. If the ARI valves do open inadvertently, a reactor scram will occur resulting in plant shutdown. This event has been analyzed and is not a new or different kind of accident. The ARI system is designed with redundant trip systems in order to help ensure system function when required. The system design features do not create the possibility of a new or different kind of accident from any previously analyzed.

c. The rerouting of the SLCS discharge piping and the relocation of the low point drain will not create a new or different path for drywell bypass leakage because adequate isolation is provided at the drywell penetration. Therefore, there is no possibility of a new or different kind of accident from any previously analyzed.

The possibility of a new or different kind of accident is not created by the movement of the Class 1 boundary from the F004 (A & B) valves to the F006 valve because the Class 2 components are isolated from the reactor coolant system by two normally closed ASME Class 1 valves.

The proposed increase in the SLCS pump relief valve setpoint does not adversely affect the safety function performed by SLCS or the operability of the SLCS system. The increase in SLCS design pressure does not affect any accident precursors and cannot create the possibility of a new or different kind of accident from any previously evaluated.

3. The proposed amendment does not involve a significant reduction in a margin of safety.

a. The proposed revisions are in accordance with the requirements of 10 CFR 50.62, and provide additional assurance that systems exist that are capable of safely shutting down the reactor should an ATWS event occur. The ATWS-RPT and SLCS systems operability do not decrease the margin of safety since they serve as backups to other safety-related systems.

The proposed change in the ARI/RPT reactor pressure-high trip setpoint does not involve a significant reduction in a margin of safety. As stated in AECM-87/0152 dated August 13, 1987, the basis for the new ATWS reactor pressure high setpoint is to ensure that the relief valve capacity below the Nominal Trip Setpoint (NTSP) is less than 15% Nuclear Boiler Rated (NBR) when operating at less than rated power. This steam flow limitation allows 10 minutes for SLCS initiation without exceeding the suppression pool temperature limit of 185°F.

The design basis event for this setpoint is Main Steam Isolation Valve (MSIV) closure with a subsequent failure to scram. The safety limit is peak Reactor Pressure Vessel (RPV) bottom pressure of 1375 psig for active components. The current setpoint was established such that this safety limit would not be exceeded. Lowering the setpoint will increase the safety margin by initiating ARI and RPT earlier in the event, thereby

providing additional margin to the safety limit.

The normal Reactor Protection System (RPS) scram path setpoint is 1064.7 psig based on an analytic limit of 1095 psig. Therefore, since the ATWS RPV pressure high NTSP is less than or equal to 1095 psig, it is possible (but highly unlikely) under extremes of instrument accuracy and drift to initiate the ATWS ARI and RPT functions prior to the normal RPS scram. However, since the ARI and normal scram paths perform the same function (i.e., insert all control rods) this would not be of any safety significance.

Additionally, tripping the recirculation pumps via the ATWS RPT prior to the normal RPS scram would only serve to minimize the pressure rise in the RPV in the first few seconds of the event and to reduce the reactor thermal power which in turn reduces steam flow which might need to be discharged to the suppression pool. Therefore, initiation of the ARI and RPT functions prior to the normal RPS scram is of no safety significance and does not involve a significant reduction in a margin of safety.

b. The connection of the ARI valves to the RPT trip system will not adversely impact the RPT function. The ARI system serves as a backup to the normal reactor scram system by depressurizing the scram pilot air header. Therefore, installation of the ARI system will increase the margin of safety during an ATWS event.

c. The current amount of suppression pool bypass leakage that would occur during a LOCA is not affected by the modified SLCS piping design. The modified piping will be constructed to the Class 1 standards of ASME Section III and Seismic Category I requirements and will be provided with adequate isolation capability.

The margin of safety is not decreased by the movement of the Class 1 boundary from the F004 (A & B) valves to the F006 valve because the safety function of isolating the reactor coolant system from Class 2 portions of the systems is still maintained by the ASME Class 1 [isolation] valves (F006 and F007).

The increase in the SLCS pump relief valve setpoint is in accordance with the ASME Code. The proposed change will provide additional assurance that the SLCS will be able to deliver its rated flowrate to the reactor without the possibility of some flow being diverted through the relief valve. The proposed change will allow an upgrade in SLCS design pressure to 1500 psig which will increase the present margin to the relief valve setpoint by 100 psi. As such, the proposed change will increase the margin of safety.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has made a preliminary review of the licensee's analysis and agrees with the licensee's conclusions that the three standards in 10 CFR 50.92 are met for the proposed changes in TS for Grand Gulf Nuclear Station, Unit 1. Accordingly, the Commission proposes to determine that the requested changes

to the TS do not involve significant hazards considerations.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Written comments may be addressed to the Rules and Records Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this *Federal Register* notice. Copies of comments received may be examined at the NRC Public Document Room, 1717 H Street NW., Washington, DC.

By January 4, 1988, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Requests for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene.

Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene, which must include a list of the contentions that are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period, such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will

publish a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street NW., Washington, DC, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325-6000 (in Missouri (800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to Elinor G. Adensam: Petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this *Federal Register* notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Nicholas S. Reynolds, Esquire, Bishop, Liberman, Cook, Purcell, and Reynolds, 1200 17th Street NW., Washington, DC 20036, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board designated to rule on the petition and/or request, that the petitioner has made a substantial showing of good cause for the granting of a late petition and/or request. That determination will be based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated August 13, 1987 as revised October 23, and November 25, 1987, which is available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, DC 20555, and at the Local Public Document Room, Hinds Junior College, McLendon Library, Raymond, Mississippi 39154.

Dated at Bethesda, Maryland, this 1st day of December 1987.

For the Nuclear Regulatory Commission.
Brenda R. Mozafari,
Acting Project Manager, Project Directorate II-1, Division of Reactor Projects I/II.
 [FR Doc. 87-27882 Filed 12-3-87; 8:45 am]
 BILLING CODE 7590-01-M

[Docket No. 50-443-OL-1 & 50-444-OL-1]

Reconstitution of Atomic Safety and Licensing Appeal Board; Public Service Co. of New Hampshire et al. (Seabrook Station, Units 1 and 2)

Notice is hereby given that, in accordance with the authority conferred by 10 CFR 2.787(a), the Chairman of the Atomic Safety and Licensing Appeal Panel has reconstituted the Atomic Safety and Licensing Appeal Board for this operating license proceeding for the limited purposes of hearing the intervenor's appeal from the Licensing Board's August 20, 1987 memorandum and order denying their petition to require the applicants to demonstrate financial qualification to operate and decommission the Seabrook facility. As reconstituted for this limited purpose, the Appeal Board will consist of:

Alan S. Rosenthal, Chairman
 Thomas S. Moore
 Howard A. Wilber
 C. Jean Shoemaker,
Secretary to the Appeal Board.

Dated: November 30, 1987.

[FR Doc. 87-27880 Filed 12-3-87; 8:45 am]
 BILLING CODE 7590-01-M

[Docket No. 50-416]

Mississippi Power & Light Co. et al.; Consideration of Issuance of Amendment to Facility Operating License and Opportunity for Prior Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF-29 issued to Mississippi Power & Light Company, System Energy Resources, Inc., and South Mississippi Electric Power Association, for operation of the Grand Gulf Nuclear Station (GGNS), Unit 1, located in Claiborne County, Mississippi.

System Energy Resources, Inc. (SERI or the licensee) requested a license amendment by letter dated October 28, 1987, as revised November 25, 1987. The proposed license amendment would revise the provisions in the Technical Specifications (TS) related to an interchange in the power supply between two isolation valves (F252 and

F253) in the reactor water cleanup (RWCU) system.

As a result of a design review of the RWCU, the licensee discovered that an inboard containment isolation valve (F252) in a branch line had the same divisional power supply (Division A) as the outboard containment isolation valve in the main piping (F004). The inboard containment isolation valve in the main piping (F001) and the outboard drywell isolation valve in the branch line (F253) have Division B power supplied to them.

In order to prevent a single failure of a power supply from causing failure of the containment isolation function of the branch piping, the licensee proposed an interchange between the Division A power supply to valve F252 and the Division B power supply to valve F253. The license amendment requested associated TS changes to Specification 3/4.6.4 and 3/4.8.4.1.

The licensee's design review of the RWCU also disclosed that the piping components in the branch lines out to the outboard dry well isolation valve (F253) were designated ASME Boiler and Pressure Code, Class 2 (ASME Code Class 2) and not ASME Code Class 1. The Commission's regulations (10 CFR 50.55a) require that the reactor coolant pressure boundary (RCPB) include all those pressure-containing components which are connected to the reactor coolant system, up to and including the outermost containment isolation valve in system piping which penetrates primary reactor containment. For GGNS, Unit 1 which has a BWR-6 Mark III containment, the dry well is considered as the primary reactor containment structure for the purpose of establishing ASME Code Class requirements for piping. By separate letter dated November 25, 1987, the licensee requested an exemption from 10 CFR 50.55a that requires components which are a part of the RCPB to meet the requirements of ASME Code Class 1. This request for an exemption will be addressed separately by the staff.

Prior to issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

By January 4, 1988, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Requests for a hearing and petitions for leave to

intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene, which must include a list of the contentions that are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to

present evidence and cross-examine witnesses.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street, NW, Washington, DC, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner or representative for the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325-6000 (in Missouri (800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to Elinor G. Adensam: (petitioner's name and telephone number); (date petition was mailed); (plant name); and (publication date and page number of this Federal Register notice). A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Nicholas S. Reynolds, Esquire, Bishop, Lieberman, Cook, Purcell, and Reynolds, 1200 17th Street, NW, Washington, DC 20036, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board designated to rule on the petition and/or request, that the petitioner has made a substantial showing of good cause for the granting of a late petition and/or request. That determination will be based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC 20555, and at the Local Public Document Room, Hinds Junior College, McLendon Library, Raymond, Mississippi 39154.

Dated at Bethesda, Maryland, this 1st day of December 1987.

For the Nuclear Regulatory Commission,
Lester L. Kintner,

Project Manager, Project Directorate II-1,
Division of Reactor Projects I/II.

[FR Doc. 87-27883 Filed 12-3-87; 8:45 am]

BILLING CODE 7590-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-25159; File No. SR-Amex-87-24]

Self-Regulatory Organizations; American Stock Exchange, Inc., Order Approving Proposed Rule Change on an Accelerated Basis

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on September 28, 1987, the American Stock Exchange, Inc. filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II, and III below. The Commission is publishing this ORDER to solicit comments on the proposed rule change from interested persons. For the reasons described below, the Commission is approving the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rules 310, 311, 317, 341, 342 and 920 to effectuate the Exchange's participation in the CRD. The text of the proposed rule change is available at the Office of the Secretary, American Stock Exchange, Inc. and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

(1) Purpose

The American Stock Exchange intends to become a participant in the Central Registration Depository ("CRD"). The CRD is a computerized securities personnel registration processing system operated pursuant to an agreement between the National Association of Securities Dealers ("NASD") and the North American

Securities Administrators Association ("NASAA"). The CRD represents a simplified, unified approach to registration of securities personnel.

Currently, Amex member organizations which are also NASD or NYSE members must submit applications for registration of securities personnel to the CRD and provide options certification to the Amex. The CRD system will be used to process applications for registration of personnel of member organizations which are also members of the NASD or the NYSE. Applications will continue to be deemed to be filed with and approved by the Exchange. Therefore, Exchange participation will enable member firms to file registration information with a single entity that will process it on behalf of the three SROs.

A number of benefits are expected as a result of Exchange participation in the CRD: Subscribing to the CRD will benefit members by eliminating the need for member firms to provide the Amex with separate notification regarding options sales personnel; the Exchange will have access to an up-to-date automated system which will contain information on all registered persons; CRD will automatically approve applicants who have a clear regulatory history—only problem applications will be reviewed by individual SROs.

The Exchange proposes to charge member firms a moderate fee to cover the expenses associated with registering sales personnel. The initial fee will be \$25 for subscribing to the CRD. A \$10 transfer fee and a \$10 termination fee will be charged. There will also be a \$7 annual renewal fee to cover fixed expenses of the CRD.

In order to effectuate the Exchange's participation in the CRD, technical changes to Rules 310 (Formation of or Admission to Member Organizations), 311 (Member Organization Changes), 317 (Formation of Corporate Affiliates), 341 (Approval of Registered Employees and Officers), 342 (Association of Members, Member Organizations and Persons Associated With Member Organizations), and 920 (Registration and Examination of Options Personnel) are necessary. These changes will make it clear that any filing or submission required under these rules made with CRD as an authorized agent of the Exchange will be deemed to be a filing with the Exchange. The Exchange will announce to its membership, through an Information Circular, the revised submission procedures for applications as a result of its participation in the CRD.

(2) Basis

The proposed rule change is consistent with section 6(b) of the Act in general and furthers the objectives of section 6(b)(5) in particular in that it will foster cooperation and coordination among self-regulatory organizations engaged in regulating persons handling securities transactions.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change will impose no burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The American Stock Exchange, Inc. requests that the proposed rule change be given accelerated effectiveness pursuant to section 19(b)(2) of the Act because such action will foster uniformity among the national securities exchanges in processing applications for approval of certain associated persons by member organizations.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a securities exchange, and in particular, the requirements of section 6 and the rules and regulations thereunder.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof in that such action will foster uniformity among the national securities exchanges in processing applications for approval of certain associated persons by member organizations. The NASD developed the automated system in 1980 and the NYSE subscribed to the CRD in 1985. The American Stock Exchange Inc's participation in the CRD system will allow it to take advantage of established CRD procedures for the registration of member organization personnel.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW.,

Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by December 28, 1987.

It Is Therefore Ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change referenced above be, and hereby is, approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority, 17 C.F.R. 200.30-3(a)(12).

Dated: November 30, 1987.

Jonathan G. Katz,
Secretary.

[FR Doc. 87-27834 Filed 12-3-87; 8:45 am]
BILLING CODE 8010-01-M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Midwest Stock Exchange, Inc.

November 30, 1987.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the following stocks:

Hanson Trust PLC
Warrants expiring September 30, 1994
(File No. 7-0751)
Harman International Industries, Inc.
Common Stock, \$.01 Par Value (File No. 7-0752)
Thomson McKinnon Asset Management LP
Units (File No. 7-0753)
Atlantic Energy, Inc.
Common Stock, \$3.00 Par Value (File No. 7-0754)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before December 21, 1987,

written data, views and arguments concerning the above-referenced applications. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the applications if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 87-27830 Filed 12-3-87; 8:45 am]
BILLING CODE 8010-01-M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Midwest Stock Exchange, Inc.

November 30, 1987.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the following stocks:

American Medical Buildings,
Inc. Common Stock, \$.10 Par Value
(File No. 7-0712)
ABI American Businessphones
Common Stock, \$.01 Par Value (File
No. 7-0713)
Ambrit, Inc.
Common Stock, No Par Value (File
No. 7-0714)
American Biltrite, Inc.
Common Stock, No Par Value (File
No. 7-0715)
American Capital Corporation
Common Stock, \$.10 Par Value (File
No. 7-0716)
ACME Precision Products Inc.
Common Stock, \$1.00 Par Value (File
No. 7-0717)
Atlas Consolidated Mining and
Development Corporation
Class B Common Stock, 10 Ph Pesos
(File No. 7-0718)
American Cablesystem
Class A Common Stock, \$.01 Par
Value (File No. 7-0719)
ACME United Corporation
Common Stock, \$2.50 Par Value (File
No. 7-0720)
Action Industries, Inc.
Common Stock, \$.10 Par Value (File

No. 7-0721)
 Audiotronics Corp.
 Common Stock, \$1.00 Par Value (File No. 7-0722)
 Adams Resources & Energy Inc.
 Common Stock, \$.10 Par Value (File No. 7-0723)
 Angelo Energy, Inc.
 Common Stock, \$.10 Par Value (File No. 7-0724)
 Air Express International Corporation
 Common Stock, \$.01 Par Value (File No. 7-0725)
 American Fructose Corp.
 Common Stock, Class A, \$.10 Par Value (File No. 7-0726)
 American Fructose Corp.
 Common Stock Class B, \$.10 Par Value (File No. 7-0727)
 Alpine Group Inc. (The)
 Common Stock, \$.10 Par Value (File No. 7-0728)
 ABM Gold Corp.
 Class A Common Stock, No Par Value (File No. 7-0729)
 Alpha Industries Inc.
 Common Stock, \$.25 Par Value (File No. 7-0730)
 American Healthcare Management
 Common Stock, \$.10 Par Value (File No. 7-0731)
 Altex Industries Inc.
 Common Stock, \$.01 Par Value (File No. 7-0732)
 American Israeli Paper Mills Ltd.
 Ordinary Shares, 10 SKL (File No. 7-0733)
 Anderson Jacobson Inc.
 Common Stock, \$.10 Par Value (File No. 7-0734)
 American Technical Ceramics Corp.
 Common Stock, \$.01 Par Value (File No. 7-0735)
 Armel, Inc.
 Common Stock, \$.001 Par Value (File No. 7-0736)
 Amwest Insurance Group
 Common Stock, \$.01 Par Value (File No. 7-0737)
 American List Corporation
 Common Stock, \$.01 Par Value (File No. 7-0738)
 Andrea Radio Corp.
 Common Stock, \$.50 Par Value (File No. 7-0739)
 Angeles Finance Partners
 Common Stock, No Par Value (File No. 7-0740)
 Angeles Corp.
 Common Stock, No Par Value (File No. 7-0741)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before December 21, 1987, written data, views and arguments

concerning the above-referenced applications. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the applications if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 87-27831 Filed 12-3-87; 8:45 am]

BILLING CODE 8010-01-M

**Self-Regulatory Organizations;
 Applications for Unlisted Trading
 Privileges and of Opportunity for
 Hearing; Philadelphia Stock Exchange,
 Inc.**

November 30, 1987.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the following securities:

First Bank System, Inc.

Common Stock, \$1.25 Par Value (File No. 7-0742)

Kay Jewelers, Inc.

Common Stock, \$5.00 Par Value (File No. 7-0743)

Republic New York Corp.

Common Stock, \$.01 Par Value (File No. 7-0744)

TGI Friday's Inc.

Common Stock, \$1.00 Par Value (File No. 7-0745)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before December 21, 1987, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted

trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 87-27832 Filed 12-3-87; 8:45 am]

BILLING CODE 8010-01-M

**Self-Regulatory Organizations;
 Applications for Unlisted Trading
 Privileges and of Opportunity for
 Hearing; Philadelphia Stock Exchange,
 Inc.**

November 30, 1987.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the following securities:

Diversified Energies, Inc.

Common Stock, \$1.00 Par Value (File No. 7-0746)

Jostens, Inc.

Common Stock, \$0.33 1/3 Par Value (File No. 7-0747)

ONEOK, Inc.

Common Stock, No Par Value (File No. 7-0748)

Vista Chemical Company

Common Stock, \$.01 Par Value (File No. 7-0749)

Harman International Industries, Inc.

Common Stock, \$.01 Par Value (File No. 7-0750)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before December 21, 1987, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,
Secretary

[FR Doc. 87-27833 Filed 12-3-87; 8:45 am]

BILLING CODE 8010-01-M

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

ACTION: Notice of Reporting Requirements Submitted for Review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the *Federal Register* notifying the public that the agency has made such a submission.

DATE: Comments should be submitted on or before January 4, 1988. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

Copies: Request for clearance (S.F. 83), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer. Submit comments to the Agency Clearance Officer and the OMB Reviewer.

FOR FURTHER INFORMATION CONTACT:

Agency Clearance Officer: William Cline, Small Business Administration, 1441 L Street, NW., Room 200, Washington, DC 20416, Telephone: (202) 653-8538

OMB Reviewer: Robert Neal, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503, Telephone: (202) 395-7340.

Title: SBA Long-Term Counseling Questionnaire

Form No.: SBA 1434

Frequency: On occasion

Description of Respondents: The information is collected from a randomly sampled group of small business people receiving long term counseling assistance.

Annual Response: 12,000

Annual Burden Hours: 4,000

November 24, 1987.

William Cline,
Chief, Administrative Information Branch.
[FR Doc. 87-27856 Filed 12-3-87; 8:45 am]

BILLING CODE 8025-01-M

Region I Advisory Council Meeting; Connecticut

The U.S. Small Business Administration Region I Advisory Council, located in the geographical area of Hartford, Connecticut, will hold a public meeting at 7:00 a.m., on Monday, December 14, 1987, at Valle's Steak House, 165 Brainard Road (Brainard Road Exit I-91), Hartford, Connecticut, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call Henry A. Povinelli, District Director, U.S. Small Business Administration, 330 Main Street, Hartford, Connecticut 06106, (203) 240-4670.

Jean M. Nowak,
Director, Office of Advisory Council.
November 25, 1987.

[FR Doc. 87-27857 Filed 12-3-87; 8:45 am]

BILLING CODE 8025-01-M

Region VII Advisory Council Meeting; Kansas

The U.S. Small Business Administration Region VII Advisory Council, located in the geographical area of Wichita, will hold a public meeting at 11:30 a.m., on Wednesday, December 9, 1987, in the Executive Dining Room, Fourth Financial Center, Broadway at Douglas, Wichita, Kansas, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call Clayton Hunter, District Director, U.S. Small Business Administration, 110 East Waterman, Wichita, Kansas, (316) 269-6566.

Jean M. Nowak,
Director, Office of Advisory Councils.
November 25, 1987.

[FR Doc. 87-27858 Filed 12-3-87; 8:45 am]

BILLING CODE 8025-01-M

[License No. 02/02-0506]

Application for a Small Business Investment Company License; Republic SBI Corp.

An application for a license to operate a small business investment company under the provisions of the Small Business Investment Act of 1958, as amended (15 U.S.C. 661 *et seq.*) has been filed by Republic SBI Corporation, 452 Fifth Avenue, New York, New York 10018 (Applicant), with the Small Business Administration (SBA) pursuant to 13 CFR 107.102 (1987).

The officers, directors, and sole shareholder of the Applicant are as follows:

Name and address	Position	Percent of ownership
Walter H. Weiner, 1025 Fifth Avenue, New York, New York 10028.	President & Director.	
Robert V. Treanor, 75 Tarence Street, Rockville Center, New York 11570.	Senior Vice President.	
Herbert J. Richman, Five Kington Terrace, Morganville, New Jersey 07751.	Vice President.....	
William I. Rosenblum, Jr., 199 Highland Road, Scarsdale, New York 10583.	Secretary.....	
William C. Bommer, 77 Holly Avenue, Staten Island, New York 10308.	Controller & Treasurer.	
Patricia D. Jurman, 270 Marin Boulevard, Apt. 16L, Jersey City, New Jersey 07302.	Assistant Secretary.	
Debra A. Perez, 43-17 34th Avenue, Long Island City, New York 11101.	Assistant Secretary.	
Jacqueline R. Pepe, 1029 Fenwood Drive, Valley Stream, New York 11580.	Assistant Secretary.	
Dov C. Schleim, 210 West Street, White Plains, New York 10605.	Assistant Secretary.	
Jeffrey C. Keil, 3 Pierrepont Place, Brooklyn Heights, New York 11201.	Director.....	
Ernest Ginsberg, 400 East 56 Street, Apt. 4A, New York, New York 10022.	Director.....	
Republic National Bank of New York, Fifth Avenue at 40th Street, New York, New York 10018.	Sole Shareholder..	100

Republic New York Corporation, Fifth Avenue at 40th Street, New York, New York 10018 owns 100 percent of Republic National Bank of New York. Approximately 33 percent of the outstanding stock of Republic New York Corporation is owned by Saban S.A.; Avenida Justo Arosemena, 4 Cable 32 Este, Panama City, Republic of Panama, a Panamanian corporation, all of the outstanding stock of which is owned by Mr. Edward J. Safra, 56 Rue Moillebeau, Geneva, Switzerland.

The Applicant, a Maryland Corporation, will begin operations with \$2,000,000 paid in capital and paid in surplus. The Applicant will conduct its activities primarily in New York City and the surrounding metropolitan area but will consider investments in businesses in other areas in the United States.

Matters involved in SBA's consideration of the application include the general business reputation and character of the proposed owner and management, and the probability of successful operations of the company under their management, including adequate profitability and financial soundness in accordance with the Small Business Investment Act of 1958, as

amended, and the SBA Rules and Regulations.

Notice is further given that any person, not later than 30 days from the date of publication of this Notice, submit written comments on the proposed Applicant. Any such communication should be addressed to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 "L" Street, NW., Washington, DC 20416.

A copy of the Notice shall be published in a newspaper of general circulation in New York, New York.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Robert G. Lineberry,
Deputy Associate Administrator for Investment.

Dated: November 25, 1987.

[FR Doc. 87-27859 Filed 12-3-87; 8:45 am]

BILLING CODE 8025-01-M

Region IX Advisory Council; Public Meeting

The U.S. Small Business Administration Region IX Advisory Council, located in the geographical area of San Francisco, will hold a public meeting at 10:00 a.m. on Thursday, December 10, 1987, 211 Main Street—5th Floor—Room 543, San Francisco, California, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call the Office of District Director, San Francisco District Office, 211 Main Street—4th Floor, San Francisco, California 94105, (415) 974-0642.

Jean M. Nowak,
Director, Office of Advisory Councils.
November 19, 1987.

[FR Doc. 87-27908 Filed 12-3-87; 8:45 am]

BILLING CODE 8025-01-M

Region V Advisory Council; Public Meeting

The U.S. Small Business Administration Region V Advisory Council, located in the geographical area of Indianapolis, Indiana, will hold a public meeting at 9:30 a.m. on Thursday, December 15, 1987, in the School of Business, Room 4095 at Indiana University-Purdue University at Indianapolis, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For Further information, write or call the Robert D. General, District Director,

U.S. Small Business Administration,
Minton-Capehart Federal Building,
Room 578, 575 North Pennsylvania
Street, Indianapolis, Indiana 46204-1584
(317) 269-7275.

Jean M. Nowak,
Director, Office of Advisory Councils.

November 30, 1987.

[FR Doc. 87-27909 Filed 12-3-87; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Order 87-11-53, Docket 45026]

Application of Air Ruidoso, Ltd. for Certificate Authority Under Subpart Q

AGENCY: Department of Transportation.

ACTION: Notice of order to show cause.

SUMMARY: The Department of Transportation is directing all interested persons to show cause why it should not issue an order finding Air Ruidoso, Ltd., fit and awarding it a certificate of public convenience and necessity to engage in interstate and overseas scheduled air transportation.

DATES: Persons wishing to file objections should do so no later than December 16, 1987.

ADDRESSES: Objections and answers to objections should be filed in Docket 45026 and addressed to the Documentary Services Division (C-55, Room 4107), U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590 and should be served upon the parties listed in Attachment A to the order.

FOR FURTHER INFORMATION CONTACT: Mrs. Mary Catherine Terry, Air Carrier Fitness Division (P-56, Room 6420), U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366-2343.

Dated: November 30, 1987.

Matthew V. Scocozza,
Assistant Secretary for Policy and International Affairs.

[FR Doc. 87-27835 Filed 12-3-87; 8:45 am]

BILLING CODE 4910-82-M

Coast Guard

[CGD 87-086]

Rules of the Road Advisory Council; Meeting

AGENCY: Coast Guard, DOT.

ACTION: Notice of meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5

U.S.C. App. 2), notice is hereby given of a meeting of the Rules of the Road Advisory Council (RORAC). A meeting of the Rules of the Road Advisory Council will be held Monday thru Wednesday, January 25-27, 1988. The meeting will be held at the Seattle Sheraton Hotel & Towers, 1400 Sixth Avenue, Seattle, Washington, and is scheduled to begin at 8:30 a.m. and end at 4:30 p.m. each day. The agenda for the meeting includes the following items:

1. Working Group meetings on Monday, January 25th, to discuss issues dealing with Lights and Shapes, COLREGS, Pilot Rules, use of Blue Lights and RORAC Publicity.

2. On Tuesday, January 26th, the major issue being considered by the Council will be the Vertical Sector Lighting Requirements for Unmanned Barges operating on COLREG waters.

3. Matters related to the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS) recently considered by the International Maritime Organization's (IMO) Assembly of November 1987.

(a) Review of proposed COLREGS amendments and their applicability to the Inland Navigation Rules.

(b) Matters to be considered at the IMO's 34th session of the Sub-committee on Safety of Navigation (SUBNAV) in February 1988.

4. Brief update on Coast Guard Status Reports and Information Items.

5. Proposals by U.S. Navy to amend the Navigation Rules and Annexes by providing the Council with the results of recent restricted in ability to maneuver light tests.

6. Any matters properly brought before the Council.

The Council is interested in hearing the advice from individual attendees and interested parties concerning the Vertical Sector Lighting Requirements for Unmanned Barges. Persons interested in addressing the Council on this issue, particularly persons with expertise and experience with the navigational lighting systems used on unmanned barges, battery power sources, barge lighting appliances, towing vessel operations, pilotage, and operation of commercial and recreational vessels, should contact the Executive Director. The technology available to meet the vertical sector light requirements of Annex I to the Navigation Rules and problems associated with meeting the requirements will be considered by the Council.

Attendance is open to the public. With advance notice, members of the public may present oral statements at the

meeting. Persons wishing to present oral statements should notify the Executive Director no later than the day before the meeting. Any members of the public may present a written statement to the Council at any time. Persons desiring to address the Council on the Unmanned Barge Vertical Sector Lighting issue are requested to contact the Executive Director of the Council prior to December 31, 1987.

Additional information may be obtained from Commander Charles K. Bell, Executive Director, Rules of the Road Advisory Council, U.S. Coast Guard (G-NSS-2), Washington, DC 20593-0001, Telephone (202) 267-0414.

Dated: November 27, 1987.

Martin H. Daniell,

Rear Admiral, U.S. Coast Guard, Chief, Office of Navigation.

[FR Doc. 87-27818 Filed 12-3-87; 8:45 am]

BILLING CODE 4910-14-M

[CGD 87-074]

Towing Safety Advisory Committee; Meeting of Subcommittee on Tank Barge Construction

AGENCY: Coast Guard, DOT.

ACTION: Notice of meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463; 5 U.S.C. App. I), notice is hereby given of a meeting of the following subcommittee of the Towing Safety Advisory Committee (TSAC):

1. The Subcommittee on Tank Barge Construction, Certification and Operations will meet on January 6, 1988 in Room 4315 at U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593-0001. The meeting will begin at 1:00 p.m. The agenda will be the following discussion item:

(a) The Coast Guard Notice of Proposed Rulemaking on Intervals for Required Internal Examination and Hydrostatic Testing of Pressure Vessel Type Cargo Tanks on Barges.

Attendance is open to the public. Members of the public may present oral or written statements at the meeting. Additional information may be obtained from the Executive Director of TSAC at U.S. Coast Guard Headquarters, Room 2110, 2100 Second Street SW., Washington, DC 20593-0001 or by calling (202) 267-1477.

Dated: November 30, 1987.

J.J. Smith,

Captain, U.S. Coast Guard, Executive Director, Towing Safety Advisory Committee.

[FR Doc. 87-27819 Filed 12-3-87; 8:45 am]

BILLING CODE 4910-14-M

Research and Special Programs Administration

Office of Pipeline Safety, Technical Pipeline Safety Standards Committee; Advisory Committee Charter

This notice announces the renewal of the Technical Pipeline Safety Standards Committee under section 14 of the Federal Advisory Committee Act (5 U.S.C. App. 1; Pub. L. 92-463) and sets forth the new charter of the Committee prepared in accordance with section 9 of that Act.

The purpose of the Technical Pipeline Safety Standards Committee is to review proposed gas pipeline safety standards and report to the Executive Director on the technical feasibility, reasonableness, and practicability of each such proposal. The Committee may propose safety standards related to gas pipeline facilities to the Executive Director for consideration.

It has been determined that renewal of the Technical Pipeline Safety Standards Committee is in the public interest in connection with the performance of duties imposed by law on the Department under section 4 of the Natural Gas Pipeline Safety Act of 1968, as amended by section 102 of the Pipeline Safety Act of 1979 (49 U.S.C. 1673).

The charter of the Committee is set forth below:

Charter—Technical Pipeline Safety Standards Committee

1. *Purpose.* This charter of the Technical Pipeline Safety Standards Committee is prepared and renewed in accordance with the Federal Advisory Committee Act (FACA) enacted October 6, 1972.

2. *Background.* Section 4 of the Natural Gas Pipeline Safety Act of 1968 (NGPSA) authorizes the establishment and prescribes the duties of the Technical Pipeline Safety Standards Committee. The Committee was established on January 2, 1969, by the appointment of 15 members. Since its establishment, the Committee has met from time to time to review and report on proposed Federal gas pipeline safety standards submitted to it by the Department.

3. *Sponsor.* The Office of Pipeline Safety is the Committee sponsor. The Assistant Director for Pipeline Safety Regulation, Office of Pipeline Safety, is designated the Executive Director of the Committee and shall be the Department of Transportation (DOT) official authorized to call or adjourn meetings, approve the agenda, and otherwise

monitor the Committee's meetings and progress.

4. *Committee Objectives and Duties.* The Executive Director shall submit to the Committee for its consideration each notice of proposed gas pipeline safety standards (including both new standards and amendments to existing standards). Within 90 days after receipt by the Committee of any such proposal, the Committee shall prepare a report on the technical feasibility, reasonableness, and practicability of the proposal. Each report by the Committee, including any minority views, shall, if timely made, be published and form a part of the proceedings for the promulgation of standards. The Administrator, Research and Special Programs Administration, may establish a final standard at any time after the 90th day following a proposal's submission to the Committee, whether or not the Committee has reported on such proposal. The Administrator shall not be bound by conclusions of the Committee, but in the event that the conclusions of the majority of the current members of the Committee are rejected, the reasons for rejection shall be incorporated in the preamble published with the final rule (NGPSA, section 4, and 49 CFR 1.53). The Committee may propose safety standards related to gas pipeline facilities to the Executive Director for consideration. The Committee may also review and report on other matters related to the Department's gas pipeline safety rulemaking function as are presented by the Executive Director.

5. Membership.

a. The Committee shall be composed of 15 members, each of whom shall be appointed by the Secretary, after consultation with public and private agencies concerned with the technical aspect of the transportation of gas or the operation of pipeline facilities. Members shall be appointed on the basis of their experience in the safety regulation of the transportation of gas and of pipeline facilities, or their training, experience, or knowledge in one or more fields of engineering applied in the transportation of gas or the operation of pipeline facilities to evaluate gas pipeline safety standards, as follows:

(1) Five members shall be selected from Federal, State, or local governmental agencies, and two of the five shall be State commissioners selected after consultation with representatives of the national organization of State commissions;

(2) Four members shall be selected from the natural gas industry, after consultation with industry representatives, and not less than three

of the four shall be currently engaged in the active operation of natural gas pipelines; and

(3) Six members shall be selected from the general public.

b. The membership shall be fairly balanced in terms of the points of view represented, and the advice and recommendations of the Committee shall be the result of its independent judgment (FACA, section 5(b)(2) and (3)).

c. Members are appointed for a term of 3 years except that a member may serve until his successor is appointed, but for not more than a total of 6 years.

6. *Appointment of Officers.* At the first meeting of each calendar year, the Executive Director shall appoint a Chairman and Vice-Chairman, and the Committee shall, by majority vote of the members present, elect a Secretary. These three officers, who will serve until their successors are appointed, shall constitute an executive committee.

7. *Meetings and Procedures.*

a. *Calling meetings.* The Executive Director shall approve in advance the scheduling and agenda of each Committee meeting (FACA, section 10(f)). The Committee may recommend agenda items to the Executive Director. A designated officer or employee of the Federal government shall attend each Committee meeting, and is authorized to adjourn the meeting whenever he determines it to be in the public interest (FACA, section 10(e)).

b. *Presiding at meetings.* The Chairman shall preside at all meetings of the Committee and of the Executive Committee, except that the Executive Director or his delegate may preside whenever the Committee is, at the request of an official of the Department of Transportation, advising the Department on matters other than notices of proposed rulemaking. The Vice-Chairman shall assume and perform the duties of the Chairman in the event of his absence. A majority of the current members of the Committee must be present at a meeting to perform the Committee's statutory duties.

c. *Duties of Secretary.* The Committee Secretary shall, as directed by the Chairman, monitor records, summarize activities, prepare and process letter ballots, and prepare reports for submission to the Executive Director. In the absence of the Secretary, the Chairman appoints a member of the Committee to perform the duties of the Secretary.

d. *Notices of meetings.* Notice of each Committee meeting shall be published in the *Federal Register* at least 15 days in advance of the meeting, except in emergency situations. Other forms of

notice are to be used to the extent practicable (FACA, section 10(a)(2)).

e. *Frequency of Committee meetings.* The Committee meets at least twice each calendar year. In addition, Committee members may be polled or asked for comments on notices of proposed rulemaking or other matters at any time without formally assembling at one place.

f. *Public participation.* Each Committee meeting shall be open to the public except where the Executive Director of the Committee determines in writing that the meeting, or a portion thereof, shall be closed for one of the reasons specified in 5 U.S.C. 552b(c) (FACA, section 10(a)(1) and (d)). Public participation in the meeting may be limited by reasonable rules (FACA, section 10(a)(3)).

g. *Minutes.* Detailed minutes of each Committee meeting shall be kept and certified to by the Committee Chairman. The minutes shall contain a record of the persons participating, a complete and accurate description of the matters discussed and conclusions reached, and copies of all reports received, issued, or approved by the Committee (FACA, section 10(c)).

h. *Availability of records.* The records, reports, transcripts, minutes, and other documents of the Committee shall be available for public inspection and copying at the Office of Pipeline Safety, 400 Seventh Street, SW., Washington, DC 20590, subject to the Freedom of Information Act, 5 U.S.C. 552 (FACA, section 10(b)).

8. *Compensation.* Members of the Committee shall not be compensated. However, all members, while away from their homes or regular places of business, shall be allowed travel expenses, including per diem in lieu of subsistence.

9. *Duration of the Committee.* Under the provisions of the NGPSA, the Committee's purposes are continuing in nature; therefore, the Committee has an indefinite duration. The Committee itself must be renewed at successive 2-year intervals by the appropriate action of the Secretary (FACA, section 14(c)).

10. *Administrative Support.* The Executive Director is responsible for providing office space, equipment, supplies, clerical help, and other administrative and financial support for the Committee.

11. *Annual Operating Cost.* Estimated annual operating cost is approximately \$20,000 for travel and recording the proceedings, plus about one-eighth person-year of staff support.

12. *Public Interest.* The formation and use of the Technical Pipeline Safety Standards Committee is determined to

be in the public interest in connection with the performance of duties imposed on the Department by law. In fact, the NGPSA specifically requires the Department to submit all proposed gas pipeline safety standards to the Committee as part of the proceedings for the promulgation of such standards.

13. *Filing Date.* December 16, 1987. This is the effective date of the charter which will expire 2 years from that date unless sooner terminated.

Richard L. Beam,

Director, Office of Pipeline Safety.

[FR Doc. 87-27836 Filed 12-3-87; 8:45 am]

BILLING CODE 4910-60-M

DEPARTMENT OF THE TREASURY

Customs Service

[T.D.-87-149]

Reimbursable Service; Excess Cost of Preclearance Operation

November 4, 1987.

Notice is hereby given that pursuant to § 24.18(d), Customs Regulations (19 CFR 24.19(d)), the biweekly reimbursable excess costs for each preclearance installation are determined to be as set forth below and will be effective with the pay period beginning November 23, 1987.

Installation	Biweekly excess cost
Montreal, Canada.....	\$17,790
Toronto, Canada.....	33,722
Kindley Field, Bermuda.....	12,593
Nassau, Bahama Islands.....	22,992
Vancouver, Canada.....	13,284
Winnipeg, Canada.....	2,928
Freeport, Bahama Islands.....	14,791
Calgary, Canada.....	8,293
Edmonton, Canada.....	4,587

William R. Riley,

Comptroller.

[FR Doc. 87-27879 Filed 12-3-87; 8:45 am]

BILLING CODE 4820-02-M

VETERANS ADMINISTRATION

Performance Review Board Members

AGENCY: Veterans Administration.

ACTION: Notice.

SUMMARY: Under the provisions of 5 U.S.C. 4314(c)(4) agencies are required to publish a notice in the *Federal Register* of the appointment of Performance Review Boards (PRB) members. This notice revises the list of members of the Veterans Administration's Performance Review Boards which was published in the

Federal Register (51 FR 40296, date November 5, 1986).

EFFECTIVE DATE: November 1, 1987.

FOR FURTHER INFORMATION CONTACT: K. Joyce Edwards, Office of Personnel and Labor Relations (05A3), Veterans Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 233-3423.

The VA's Performance Review Boards (PRBs) will be chaired by the following individuals:

Chairperson, VA PRB

Thomas K. Harvey, Deputy Administrator

Chairperson, Department of Medicine and Surgery PRB

Arthur J. Lewis, M.D., Deputy Chief Medical Director

Chairperson, Department of Veterans Benefits PRB

David A. Brigham, Executive Assistant to the Chief Benefits Director

Chairperson, Office of Inspector General PRB

James H. Curry, Assistant Inspector General for Audit Policy and Oversight, Department of Defense

The membership of the VA's four Performance Review Boards will be selected from the aforementioned Chairpersons and the following individuals:

Raymond H. Avent, Deputy Chief Benefits Director for Field Operations

Raymond S. Blunt, Director, Office of Program Analysis and Evaluation

David A. Cox, Associate Deputy Administrator for Management

James B. Durnil, Deputy Inspector General, Agency for International Development

Kenneth E. Eaton, Chairman, Board of Veterans Appeals

Wilfred L. Ebel, Chief Memorial Affairs Director

Sidney M. Ford, Regional Director, Midwestern Region

John A. Gronvall, M.D., Chief Medical Director

Arthur S. Hamerschlag, Deputy Chief Memorial Affairs Director

Conrad R. Hoffman, Director, Office of Budget and Finance (Controller)

Grady W. Horton, Deputy Chief Benefits Director for Program Management

Paul D. Ising, Deputy Chief Benefits Director for ADP Systems Management

Donald L. Ivers, General Counsel

Frank E. Lalley, Director, Office of Information Management and Statistics

John J. Lee, Regional Director, Mid-Atlantic Region

Robert E. Lindsey, Jr., Regional Director, Western Region

Susan Livingstone, Associate Deputy Administrator for Logistics

Frederick L. Malphurs, Director, Resource Management Office

Gerald S. Martin, Assistant Chief of Staff

Richard P. Miller, Regional Director, Southwestern Region

Renald P. Morani, Deputy Inspector General

Gerald E. Neumann, Director, Office of Facilities

Robert R. Rhyne, D.D.S., Assistant Chief Medical Director for Dentistry

Michael Rudd, Director, Office of Personnel and Labor Relations

H. Robert Saldivar, Director, Office of Procurement and Supply

Robert W. Schultz, Associate Deputy Administrator for Public Affairs

Burt L. Talcott, Associate Deputy Administrator for Congressional Affairs

Donald B. Thompson, Regional Director, Southeastern Region

John Vogel, Chief Benefits Director

Albert B. Washko, Regional Director, Northeastern Region

Daniel H. Winship, M.D., Assistant Deputy Chief Medical Director for Programs and Operations

James R. Yancy, Director, Office of Equal Opportunity

Charles V. Yarbrough, Director, Management Support Office

Albert Zamberlan, Regional Director, Great Lakes Region

Dated: November 27, 1987.

Thomas K. Turnage,
Administrator.

[FR Doc. 87-27845 Filed 12-3-87 8:45 am]

BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register

Vol. 52, No. 233

Friday, December 4, 1987

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL DEPOSIT INSURANCE CORPORATION

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the previously announced meeting¹ of the Board of Directors of the Federal Deposit Insurance Corporation scheduled to be held on Tuesday, December 8, 1987 at 2:00 p.m. (open session) has been *cancelled*. Notice is also given that the previously announced meeting¹ of the Board of Directors scheduled to be held on Tuesday, December 8, 1987 at 2:30 p.m. (closed session) has been *rescheduled* for 2:00 p.m. that same day.

No earlier notice of this cancellation and of the change in the time of the meeting was practicable.

Dated: December 2, 1987.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 87-28001 Filed 12-2-87; 3:15 pm]

BILLING CODE 6714-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 2:00 p.m. on Tuesday, December 8, 1987, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous meetings.

Application for Federal deposit insurance:

American Savings Bank, an operating non-FDIC-insured federal savings bank located at 820 A Street, Tacoma, Washington.

¹ Editorial note: Published elsewhere in the Sunshine Act section of this issue.

Reports of actions approved by the standing committees of the Corporation and by officers of the Corporation pursuant to authority delegated by the Board of Directors.

Discussion Agenda:

Memorandum and resolution re: Extension of the period of time which the Corporation may use under its internal policy statement for the consideration, adoption, and publication of a final amendment to Part 332 of the Corporation's rules and regulations, entitled "Powers Inconsistent with Purposes of Federal Deposit Insurance Law."

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street, NW., Washington, DC.

Requests for further information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 898-3813.

Dated: December 1, 1987.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 87-28002 Filed 12-2-87; 3:15 pm]

BILLING CODE 6714-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is thereby given that at 2:30 p.m. on Tuesday, December 8, 1987, the Federal Deposit Insurance Corporation's Board of Directors will meet in closed session, by vote of the Board of Directors, pursuant to sections 552b(c)(2), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of Title 5, United States Code, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Recommendations with respect to the initiation, termination, or conduct of administrative enforcement proceedings (cease-and-desist proceedings, termination-of-insurance proceedings, suspension or removal proceedings, or assessment of civil money penalties) against certain insured banks or officers, directors, employees, agents or other persons participating in the conduct of the affairs thereof:

Names of persons and names and locations of banks authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(6), (c)(8), and (c)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(6), (c)(8), and (c)(9)(A)(ii)).

Note.—Some matters falling within this category may be placed on the discussion agenda without further public notice if it becomes likely that substantive discussion of those matters will occur at the meeting.

Report of the Director, Division of Liquidation:

Memorandum re:

Monthly Report of Actions Under Delegated Authority by the Committee on Liquidations, Loans and Purchases of Assets—October 1, 1987—October 31, 1987

Discussion Agenda:

Personnel actions regarding appointments, promotions, administrative pay increases, reassignments, retirements, separations, removals, etc:

Names of employees authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(2) and (c)(6) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2) and (c)(6)).

Matters relating to the possible closing of certain insured banks:

Names and locations of banks authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting will be held in the Board room on the sixth floor of the FDIC Building located at 550-17th Street NW., Washington, DC.

Requests for further information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 898-3813.

Dated: December 1, 1987.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 87-28003 Filed 12-2-87; 3:15 p.m.]

BILLING CODE 6714-01-M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

December 1, 1987.

TIME AND DATE: 10:00 a.m., Thursday, December 3, 1987.

PLACE: Room 600, 1730 K Street, NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: In addition to the previously announced items, the Commissioners will consider and act upon the following:

3. *Harley M. Smith v. Bow Valley Coal Resources, Inc.*, Docket No. KENT 86-23-D, etc. (Issues include consideration of a motion to dismiss.)

It was determined by a unanimous vote of Commissioners that this item be included and that no earlier announcement of the addition was possible.

CONTACT PERSON FOR MORE

INFORMATION: Jean Ellen (202) 653-5629.

Jean H. Ellen,

Agenda Clerk.

[FR Doc. 87-27941 Filed 12-2-87; 11:21 am]

BILLING CODE 6735-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: Approximately 11:00 a.m., Wednesday, December 9, 1987, following a recess at the conclusion of the open meeting.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Matters relating to the Plans administered under the Federal Reserve System's employee benefits program.

2. Proposed Federal Reserve Bank salary structure adjustments.

3. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

4. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE

INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Date: December 1, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-27923 Filed 12-2-87; 10:40 am]

BILLING CODE 6210-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: 10:00 a.m., Wednesday, December 9, 1987.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Summary Agenda

Because of their routine nature, no substantive discussion of the following items is anticipated. These matters will be voted on without discussion unless a member of the Board requests that an item be moved to the discussion agenda.

1. Proposed amendments to interpretations of Regulations D (Reserve Requirements of Depository Institutions) and Q (Interest on Deposits) to conform to the amended regulations.

2. Cost of Federal Reserve notes in 1988.

Discussion Agenda

3. Proposed 1988 Federal Reserve Bank budgets.

4. Any items carried forward from a previously announced meeting.

Note.—This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for \$5 per cassette by calling (202) 452-3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, DC 20551.

CONTACT PERSON FOR MORE

INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Date: December 1, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-27924 Filed 12-2-87; 10:40 am]

BILLING CODE 6210-01-M

NATIONAL TRANSPORTATION SAFETY BOARD

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: December 1, 1987, page 45709.

PREVIOUSLY ANNOUNCED TIME AND DATE: 9:30 a.m., Tuesday December 8, 1987.

CHANGE IN MEETING: A majority of the Board Members determined by recorded vote that the business of the Board required revising the agenda of this meeting and that no earlier announcement was possible. The following item has been added to the open session of the agenda:

6. Recommendation to FAA re Requirement for Test of Takeoff Warning System Before Every Flight on all Air Carrier Airplanes Equipped with Takeoff Warning Systems.

FOR MORE INFORMATION CONTACT: Bea Hardesty, (202) 382-6525.

Bea Hardesty,

Federal Register Liaison Officer.

December 2, 1987.

[FR Doc. 87-27980 Filed 12-2-87; 3:14 pm.]

BILLING CODE 7533-01-M

SECURITIES AND EXCHANGE COMMISSION

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meetings during the week of December 7, 1987:

A closed meeting will be held on Tuesday, December 8, 1987, at 2:30 p.m.

The Commissioners, Counsel to the Commissioners, the Secretary of the Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9)(A) and (10) and 17 CFR 200.402(a) (4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Fleischman, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the closed meeting scheduled for Tuesday, December 8, 1987, at 2:30 p.m., will be:

Settlement of administrative proceeding of an enforcement nature.

Institution of administrative proceeding of an enforcement nature.

Institution of injunctive action.

Settlement of injunctive action.

Status report of judicial proceeding.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Patrick Daugherty at (202) 272-3077.

Jonathan G. Katz,

Secretary.

December 1, 1987.

[FR Doc. 87-27958 Filed 12-2-87; 12:09 pm]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: (52 FR 45527 November 30, 1987).

STATUS: Closed meeting.

PLACE: 450 5th Street, NW., Washington, DC.

DATE PREVIOUSLY ANNOUNCED: Monday, November 23, 1987.

CHANGES IN THE MEETING: Deletion/ additional items.

The following item was not considered at a closed meeting on Tuesday, December 1, 1987, at 10:30 a.m.:

Institution of injunctive action.

The following additional items were considered at a closed meeting on

Tuesday, December 1, 1987, at 10:30 a.m.:

Institution of administrative proceeding of an enforcement nature.

Settlement of administrative proceeding of an enforcement nature.

Action involving discussion of investigative techniques.

Commissioner Fleischman, as duty officer, determined that Commission business required the above changes.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Nancy Morris at (202) 272-2468.

Jonathan G. Katz,

Secretary.

December 1, 1987.

[FR Doc. 87-27959 Filed 12-2-87; 8:45 am]

BILLING CODE 8010-01-M

Corrections

Federal Register

Vol. 52, No. 233

Friday, December 4, 1987

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents and volumes of the Code of Federal Regulations.

These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

On page 44970, in the first column, in the authority citation, in the fourth line, "2027(18)" should read "2072(18)".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA-940-07-4220-10; CA 20624]

California; Filing of Withdrawal Application

Correction

In notice document 87-23142 beginning on page 37534 in the issue of Wednesday, October 7, 1987, make the following correction:

On page 37534, in the third column, in the land description, under T. 25, N., R. 9 E., in the fourth line, "S½SE¼SW¼," should read "S½SE¼SW¼NW¼,".

BILLING CODE 1505-01-D

FARM CREDIT ADMINISTRATION

12 CFR Part 614

Farm Credit System Regulatory Accounting Practices—Temporary Regulations; Loan Policies and Operations—Loss Sharing Agreements

Correction

In rule document 87-27045 beginning on page 44969 in the issue of Tuesday, November 24, 1987, make the following correction:

Final Rule

**Friday
December 4, 1987**

Part II

Department of Labor

**Occupational Safety and Health
Administration**

**29 CFR Parts 1910 and 1926
Occupational Exposure to Formaldehyde;
Final Rule**

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910 and 1926

[Docket Nos. H-225, 225A, 225B]

Occupational Exposure to Formaldehyde

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Final rule.

SUMMARY: OSHA hereby promulgates a revised occupational safety and health standard for occupational exposure to formaldehyde, 29 CFR 1910.1048. This standard reduces the permissible exposure limits (PELs) from 3 parts formaldehyde per million parts of air (ppm) to 1 ppm as an 8-hour time-weighted average (TWA). The peak allowable exposure of 10 ppm (for up to 30 minutes) is revoked and the 5 ppm ceiling is reduced to 2 ppm as a 15-minute short term exposure limit (STEL). An "action level" of 0.5 ppm, measured as an 8-hour TWA, is included to minimize the compliance burden for employers whose employees have exceedingly low exposures to formaldehyde. The standard also contains provisions for employee exposure monitoring, medical surveillance, recordkeeping, regulated areas, emergency procedures, preferred methods to control exposure, maintenance and selection of personal protective equipment, and hazard communication. The standard applies to all industries covered by the Occupational Safety and Health Act, including construction, maritime, and general industries.

DATES: *Effective date:* This amended standard takes effect on February 2, 1988, except for the following paragraphs which contain information collection requirements which are under review at the Office of Management and Budget (5 CFR Part 1320): § 1910.1048 (d)(1)(i), (d)(2), (d)(3), (d)(4), (d)(6), (g)(3)(i), (g)(3)(ii), (l)(3), (l)(4), (l)(5), (l)(6), (l)(7), (m)(1), (m)(2), (m)(3), (m)(4), (n)(3), (n)(4), and (o). A notice will be published when the information collection requirements are approved.

ADDRESSES: For additional copies of this standard, contact: OSHA Office of Publications, U.S. Department of Labor, Room N-3101, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone (202) 523-9667.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, Director, Office of Information and Consumer Affairs,

Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3649, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone (202) 523-8151.

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I. Introduction

The standard applies to all occupational exposures to formaldehyde. This includes exposures in foundries, in apparel manufacturing, in the health care industry, in cosmetology, in the construction industry, and in general office environments.

"Formaldehyde" is defined simply as the chemical entity, HCHO, as covered under the Chemical Abstracts Service Registry No. 50-00-0. Thus, the standard applies to formaldehyde gas, its solutions, and a variety of materials, such as trioxane, paraformaldehyde, hexamethylenetetramine, and resin

formulations from which formaldehyde may be generated. Solids and any mixture containing formaldehyde are included in this standard to the extent that they are sources of formaldehyde exposure.

As was noted in the proposed rule [50 FR 50412, December 10, 1985], the construction industry currently has its own standard for formaldehyde exposure, 29 CFR 1926.55(a), which references the "Threshold Limit Values of Airborne Contaminants for 1970" of the American Conference of Governmental Industrial Hygienists. That standard, in effect, states that exposures at concentrations above 5 ppm, as a 30-minute ceiling, "shall be avoided." In the course of drafting the proposed rule, OSHA considered whether the revised general industry standard should supersede the construction industry standard. The Agency provided the Advisory Committee on Construction Safety and Health (ACCSH) with copies of the draft proposal, under which construction workers would be covered and, on September 25, 1985, formally consulted with the Committee. The ACCSH recommended that OSHA reduce construction industry formaldehyde exposure by revising the construction standard, but also agreed that, at least as an interim measure, the construction industry should be included within the scope of the revised standard. OSHA has determined that, notwithstanding the unique circumstances which may arise at a construction worksite, it is appropriate to cover construction workers under this standard.

II. Pertinent Legal Authority*The OSH Act*

The primary purpose of the Occupational Safety and Health Act (the Act) (29 U.S.C. 655 *et seq.*) is to assure, so far as possible, safe and healthful working conditions for every American worker over the period of his or her working lifetime. One means prescribed by the Congress to achieve this goal is the mandate given to, and the concomitant authority vested in, the Secretary of Labor to set mandatory safety and health standards. The Congress specifically mandated that:

The Secretary, in promulgating standards dealing with toxic materials, or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his

working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of standards, and experience gained under this and other health and safety laws (Section 6(b)(5)).

Under section 6(b)(7), standards must, where appropriate, require labels or other appropriate forms of warning to apprise employees of hazards, suitable protective equipment, exposure control procedures, monitoring and measuring of employee exposure, employee access to the results of monitoring, appropriate medical examinations, and training and education. Moreover, where a standard prescribes medical examinations or other tests, they must be available at no cost to the employees. Standards may also prescribe recordkeeping requirements where necessary or appropriate for enforcement of the Act or for developing information regarding occupational accidents and illness (section 8(c)).

Authority for issuance of this final standard is found primarily in sections 6(b), 8(c), and 8(g)(2) of the Act. Section 6(b)(5) governs the issuance of occupational safety and health standards dealing with toxic materials or harmful physical agents. Section 8(c) of the Act empowers the Secretary to require employers to make, keep, and preserve records regarding activities related to the Act. In particular, section 8(c)(3) gives the Secretary authority to require employers to "maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6." Section 8(g)(2) of the Act empowers the Secretary to "prescribe such rules and regulations as he may deem necessary to carry out [his] responsibilities under the Act."

Section 3(8) of the Act, 29 U.S.C. 652(8), defines an occupational safety and health standard as follows:

(A) Standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide a safe or healthful employment and places of employment.

The Supreme Court has held that section 3(8) must be applied to the issuance of a permanent standard to determine that the standard is reasonably necessary and appropriate to remedy a significant risk of material health impairment (*Industrial Union Department v. American Petroleum Institute*, 448 U.S. 607 (1980)). This

"significant risk" determination constitutes a finding that, in the absence of the changes in practices mandated by the standard, the workplaces in question would be "unsafe" in the sense that workers would be threatened with a significant risk of harm (*Id.* at 642).

After OSHA has determined that a significant risk exists and that such risk can be reduced or eliminated by the standard, it must set the standard, "which most adequately assures, to the extent feasible on the basis of the best available evidence, that no employees will suffer material impairment of health" (section 6(b)(5) of the Act). The Supreme Court has interpreted this section to mean that OSHA must enact the most protective standard possible to eliminate a significant risk of material impairment of health, subject to the constraints of technological and economic feasibility (*American Textile Manufacturers Institute, Inc. v. Donovan*, 452 U.S. 490 (1981)).

State Plans

The 25 States with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within six months of the publication date of this final standard. These States are: Alaska, Arizona, California, Connecticut,¹ Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York,¹ North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Until such time as a State standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate.

III. Events Leading to the Final Standard

History of the Regulation of Formaldehyde

The general industry standard for formaldehyde (29 CFR 1910.1000, Table Z-2) that is being revised required employers to ensure that employee exposure does not exceed three parts of formaldehyde per million parts of air (ppm), determined as an eight-hour time-weighted average (TWA) concentration. Furthermore, an employee's exposure to formaldehyde was not to exceed 5 ppm at any time during an eight-hour workshift, except for a maximum duration of 30 minutes, when the "acceptable maximum peak" concentration was not to exceed 10 ppm. OSHA adopted this standard in 1971 as a national consensus standard under

section 6(a) of the OSH Act (29 U.S.C. 655). The source of the formaldehyde standard was the American National Standards Institute (ANSI) (Z37.16-1967 Acceptable Concentrations of Formaldehyde) [Ex. 42-9]. The ANSI standard was designed to address formaldehyde's irritant effects on the eyes and respiratory system; offensive odor; and interference with sleep.

In 1946, the American Conference of Governmental Industrial Hygienists (ACGIH) set a 10 ppm threshold limit value (TLV) for formaldehyde which was lowered in 1948 to 5 ppm. In 1963, the ACGIH responded to reports documenting formaldehyde's irritant effects by setting a 5 ppm ceiling limit. It was this ACGIH TLV, which was still in effect in 1970, which was adopted under the Construction Safety Act and was incorporated by reference in the OSHA construction standards; see 29 CFR 1926.55(a). In 1973, further reports of irritation experienced at levels well below 5 ppm led the ACGIH to lower the ceiling limit to 2 ppm (See Ex. 42-85, pp. 94-96).

In December 1976, the National Institute for Occupational Safety and Health (NIOSH) recommended that OSHA reduce the permissible exposure limit (PEL) for formaldehyde to 1 ppm measured over a 30-minute period [Ex. 42-85]. NIOSH based this recommendation on reports that a few workers experienced eye, skin, and respiratory irritation; objectionable odors; and disturbed sleep when exposed at 0.3 ppm and that complaints became widespread when concentrations exceeded 1 ppm. For exposures exceeding 0.5 ppm, NIOSH also recommended increased exposure monitoring, medical surveillance, and associated recordkeeping.

On October 8, 1979, the Chemical Industry Institute of Toxicology (CIIT) sent preliminary findings of an animal bioassay to the EPA under procedures established by section 8(e) of the Toxic Substances Control Act (TSCA). This notification of substantial risk (No. 79-314) indicated that squamous cell carcinomas of the nasal cavities had been observed at interim sacrifice in rats exposed to formaldehyde at 14.3 ppm. The study was completed in 1981, and final results showed nasal cancers in rats exposed at 5.6 and 14.3 ppm, benign nasal tumors in rats exposed at 2 ppm, and nasal cancers in mice exposed at 14.3 ppm [Ex. 12].

In a separate study, researchers at New York University (NYU) found that rats developed nasal cancer after exposure to 14 ppm of formaldehyde [Exs. 42-3; 42-4; 42-86], corroborating

¹ Plan covers only State and local government employees.

CIIT's finding that formaldehyde is an animal carcinogen.

In April 1980, the Federal Panel on Formaldehyde was formed. Its members were scientists from eight federal agencies, including OSHA. The panel reviewed and evaluated information on formaldehyde's chronic health effects, emphasizing the CIIT study. In November 1980, the panel concluded that it was "prudent to regard formaldehyde as posing a carcinogenic risk to humans" [Ex. 13].

The NIOSH publication, Current Intelligence Bulletin 34, "Formaldehyde * * * Evidence of Carcinogenicity" recommended handling formaldehyde as a potential occupational carcinogen [Ex. 42-86]. This 1981 document reflected NIOSH's concerns regarding potential adverse effects from chronic exposure to formaldehyde based on the findings of the CIIT and NYU studies and the conclusions drawn by the Federal panel.

In 1982, the CPSC relied on the CIIT study and consumer complaint data to ban use of urea-formaldehyde foam insulation (UFFI) in residences and schools. The ban was based on CPSC's finding that UFFI posed an unreasonable risk of injury from cancer and irritation (47 FR 14366). The ban was overturned in subsequent litigation (*Gulf South Insulation v. CPSC*, 701 F.2d 1137 (5th Cir. 1983)) when the Court held that the CPSC had failed to support its ban with substantial evidence. According to the Court, CPSC erred in relying solely on the study by CIIT to establish the risk of carcinogenicity for consumers. In addition, the Court found that consumer complaint data, which were not correlated to data measuring exposure to formaldehyde, were an inappropriate basis for determining that the "risk of injury from acute irritant effects is unreasonable" (701 F.2d at 1148).

In May 1982, the International Agency for Research on Cancer (IARC) concluded that there was sufficient evidence that formaldehyde gas is carcinogenic to rats, but that epidemiologic studies available at that time provided inadequate evidence to assess the carcinogenicity of formaldehyde in man [Ex. 42-70].

In 1983, the ACGIH included formaldehyde on its list of industrial substances suspected to be potential human carcinogens and lowered its TLV for formaldehyde to 1 ppm, measured as an 8-hour TWA. At this time the ACGIH also set a short-term exposure limit (STEL) of 2 ppm for formaldehyde [Ex. 42-8].

In its Third Annual Report on Carcinogens, published in September 1983, and in subsequent reports, the U.S. Department of Health and Human

Services (DHHS) listed formaldehyde among the substances or groups of substances that could reasonably be anticipated to act as carcinogens [Ex. 52].

In October 1983, the National Center for Toxicological Research (NCTR) sponsored a Consensus Workshop on Formaldehyde [Ex. 70-56]. The objective was to resolve controversies surrounding formaldehyde's acute and chronic health effects. Over 60 government, industry, and university scientists reviewed relevant scientific studies. Consensus reports on individual effects were produced and sent to a risk estimation panel, which attempted to develop a reasonable risk assessment for humans exposed to formaldehyde. The risk estimation panel concluded that quantitative assessment of formaldehyde's toxic effects was possible only for carcinogenicity. The panel further concluded that risk modeling for carcinogenicity should be based on the CIIT rat study, not on the human epidemiology studies available at that time.

On May 23, 1984, the EPA announced that formaldehyde exposures resulting from employment in apparel manufacturing facilities and from residence in conventional or manufactured housing potentially present significant risks of widespread harm [49 FR 21870]. EPA accordingly designated formaldehyde for priority review under section 4(f) of the Toxic Substances Control Act (TSCA). Action under section 4(f) must be based on a substance's ability to induce cancer, gene mutations, or birth defects [Ex. 42-41].

On February 11, 1985, the Department of Housing and Urban Development (HUD) completed rulemaking covering formaldehyde emissions from pressed wood products used to produce manufactured homes [49 FR 31996; 24 CFR Part 3280]. HUD regulations require that plywood and particleboard cannot emit formaldehyde in excess of 0.2 ppm and 0.3 ppm, respectively.

On February 18, 1986, the EPA announced termination of its regulatory investigation of potential risks associated with occupational exposure to formaldehyde because of OSHA's jurisdiction in the area. The EPA continued to investigate formaldehyde exposures occurring in non-occupational settings, especially those arising from use of pressed wood products made with formaldehyde-based resins.

On April 16, 1987, independent of OSHA's analysis, EPA published its assessment of the human health risks associated with formaldehyde. The risk assessment states EPA's formal position

that formaldehyde should be classified as a "group B1 probable human carcinogen" in accordance with EPA's Cancer Risk Assessment Guidelines. The finding is based on (1) "sufficient" evidence that formaldehyde causes cancer in animals, (2) "limited" evidence from human studies, and (3) other information, including short-term test results, structure-activity correlations, pharmacokinetic studies, and comparative metabolism studies. EPA's determination that human evidence is "limited" is based on nine epidemiological studies reporting statistically significant associations between site-specific respiratory neoplasms and exposure to formaldehyde or formaldehyde-containing products. EPA considered the epidemiological evidence as "limited" because of possible exposures to other agents which may have confounded the findings.

In 1987, an IARC working group examined recent epidemiological evidence on formaldehyde and upgraded its designation to category 2(A), i.e. formaldehyde is a probable carcinogen in humans (personal communications, A. Blair and R. Griesemer). IARC publications and the DHHS Annual Report on Carcinogens are considered by OSHA to be authoritative sources for identification of carcinogenic chemicals under provisions of the Hazard Communication standard (See 29 CFR 1910.1200).

The recent statements by EPA and IARC occurred after the closing of the OSHA record and played no role in OSHA's decisionmaking. The information is presented so that the positions of EPA and IARC are correctly stated.

Petition for an Emergency Temporary Standard

The United States Automobile, Aerospace, and Agricultural Implement Workers of America (UAW), joined by 13 other unions, petitioned OSHA on October 26, 1981, to issue an Emergency Temporary Standard (ETS) which would impose a number of protective requirements on employers whose employees are exposed to formaldehyde. On January 29, 1982, OSHA denied the request because there was insufficient evidence that employees were in grave danger from exposure to formaldehyde or that an ETS was needed to protect workers [Ex. 73-154]. The petitioners appealed OSHA's decision to the District Court for the District of Columbia.

On July 2, 1984, the District Court remanded the UAW's formaldehyde petition to the Agency for reconsideration, directing OSHA to treat the petition as both a request for an ETS and for the initiation of permanent rulemaking (*UAW v. Donovan*, 590 F. Supp. 747 (D.D.C. 1984)). The Court cited the Consensus Workshop on Formaldehyde as evidence that issues surrounding the regulation of formaldehyde were more sharply defined and fully documented than they had been when OSHA denied the ETS petition. The Court concluded that it would be more productive for OSHA to reconsider the ETS in light of the new data than to examine whether the initial denial was appropriate.

OSHA's Office of Risk Assessment prepared a report, entitled "Preliminary Assessment of the Health Effects of Formaldehyde" (the ORA report) [Ex. 43], to examine health issues raised in the Court's reconsideration order. Released on November 5, 1984, the ORA report also examined various quantitative risk assessments that had been used to calculate human cancer risk from the CIIT data. The ORA report and related peer review comments [Exs. 44-1 to 44-24] provided OSHA with a basis for determining the significance of the human health risks posed by exposure to formaldehyde.

On January 7, 1985, OSHA again denied the UAW petition, insofar as it requested an ETS, based on the determination that the record still did not support findings that formaldehyde posed a grave danger or that the issuance of an ETS was necessary to protect formaldehyde-exposed workers [Ex. 61].

On January 11, 1985, OSHA announced that public meetings would be held in Washington, DC on February 13-15, 1985 [50 FR 1547], to generate information and discussion which would help OSHA to decide whether or not permanent rulemaking should be initiated under section 6(b) of the Act. New information on formaldehyde's health effects and quantitative risk assessments for formaldehyde was introduced at the meetings and in post-hearing comments [Exs. 68-1 to 68-23; 69-1A to 69-34; 70-1 to 70-58, and 76-1 to 76-8].

On April 15, 1985, OSHA announced it would proceed with permanent rulemaking to reduce formaldehyde exposure, basing its decision on the determination that the existing standard did not adequately address the adverse health effects associated with occupational exposure to formaldehyde. OSHA solicited information and comments regarding existing conditions

in formaldehyde producing and using industries and the availability of technology to control formaldehyde emissions in an Advance Notice of Proposed Rulemaking (ANPR) (50 FR 15179, April 17, 1985). Forty-three comments, many of them containing new information, were received in response to the ANPR [Exs. 77-1 to 77-43].

Based on a review of the existing record, new references identified by OSHA [Exs. 73-1 to 73-189], and Health Hazard Evaluations provided by NIOSH [Exs. 78-1 to 78-81], OSHA completed a preliminary Regulatory Impact Analysis [Ex. 81] and published a proposed rule [50 FR 50412-50499] on December 10, 1985. Public hearings on the proposal were subsequently scheduled to begin on May 5, 1986 [51 FR 7584].

OSHA received 302 comments on the proposal [Exs. 80-1 to 80-302]. The comments provided a substantial amount of new information, analyses, and data.

The Public hearings were held in Washington, DC, from May 5 to 16, 1986. OSHA presented 10 expert witnesses in the areas of assessment of cancer and associated risk, control technology, industrial hygiene, neurobehavioral toxicity, pulmonary function, sensitization, and medical surveillance. Three other government agencies (NIOSH, CPSC, and the National Cancer Institute (NCI)) and 18 organizations including corporations, industry associations, unions, and public interest groups also provided testimony. Many issues were addressed at the hearing, and substantial testimony was received on an epidemiologic study, conducted by the NCI in collaboration with the Formaldehyde Institute, which had been released in February 1986. This study examined the mortality experience of over 26 thousand employees at plants where formaldehyde-containing products were produced or used.

At the close of the hearings, the presiding Administrative Law Judge ordered that OSHA provide a post-hearing comment period for the submission of additional comments, arguments, and information on issues raised at the hearing. By the close of the record 120 additional exhibits were received [Exs. 115 to 182B].

Subsequently, OSHA received new information regarding human cancer risk and new exposure data, particularly in the foundry industry. To ensure that this information could be considered in drafting the final rule, OSHA reopened the record for one month to receive public comment on this new information [51 FR 44796]. Seventeen responses were

received in the one month comment period [Exs. 201-1 to 201-17].

OSHA based its final standard on occupational exposure to formaldehyde on all of the evidence accumulated until the close of the record on January 1987. More than 1,400 Exhibits with approximately 30,000 pages of testimony and comments were received into the record of this rulemaking. Based on this record, OSHA has determined that employees exposed to formaldehyde at the existing PELs of 3-ppm as a TWA, 5-ppm as a ceiling concentration, and 10-ppm as a 30-minute peak face a significant risk of material impairment of their health.

IV. Properties, Manufacture, and Uses of Formaldehyde

Chemical Properties

The chemical "formaldehyde" is a colorless, pungent gas at room temperature with an approximate odor threshold of about 1 ppm [Ex. 73-120]. The simplest member of the aldehydes class of chemicals, formaldehyde has a molecular weight of 30.

While the term "formaldehyde" is also used to describe various mixtures of formaldehyde, water, and alcohol, the term "formalin" more precisely describes aqueous solutions, particularly those containing 37 to 50 percent formaldehyde and 6 to 15 percent alcohol stabilizer. Most formaldehyde enters commerce as formalin. Alcoholic solutions of formaldehyde are available for processes that require low water content [Ex. 73-53]. Paraformaldehyde, a solid, also serves as a source of formaldehyde gas. Formaldehyde gas, *Per se*, is not available commercially.

Pure, dry formaldehyde gas is stable in the temperature range of 80 to 100 °C. At room temperature, polymerization occurs slowly to produce a white film of polyoxymethylene on the container walls. Stability depends on purity; even traces of acids, bases, or water can accelerate the polymerization reaction [Ex. 42-87].

Formaldehyde exists in freshly prepared aqueous solution in its monohydrate form, methylene glycol. When the solution ages, polymerization products consisting of paraformaldehyde and low-molecular-weight polyoxymethylene glycols may be present. Because the polymers are, at best, sparingly soluble, they may precipitate from solution. To stabilize formaldehyde solutions against polymerization, methanol or other alcohols are added [Exs. 42-87; 73-167].

The Chemical Abstracts Service (CAS) has assigned the number "50-00-0" to formaldehyde. This number applies to both formaldehyde gas and its aqueous or alcohol-stabilized solutions.

Commercial Production

Formaldehyde is a major industrial chemical, ranked 24th in production volume in the United States [Ex. 138-F]. In 1985, 5.7 billion pounds of 37 percent formaldehyde (by weight) was produced.

Formaldehyde is produced in 49 plants in the U.S. by either of two processes: the mixed oxide catalyst process or the silver oxide catalyst process. Both processes use methanol as the product precursor and they differ in catalyst type, operating temperature, and methanol/air ratios [Ex. 70-2]. About two-thirds of the annual production is used on-site or at nearby locations. For example, a major use of formaldehyde is in the preparation of adhesive resins for use in the wood products industry. These resin-producing facilities tend to be located in lumber producing areas of the South and West [Exs. 73-53; 73-174].

Formaldehyde has a high degree of chemical reactivity because of its unique chemical structure, a carbonyl group attached to two hydrogen atoms [Ex. 73-53]. As a result it undergoes a wide variety of chemical reactions in three distinct classes: oxidation-reduction reactions, addition or condensation reactions, and self-polymerization.

Addition or condensation reactions are of great commercial importance. Addition reactions include aldol condensation, condensation with ammonia, and methylol formation. Aldol condensation of formaldehyde and acetaldehyde in the presence of alkali metal or alkaline earth hydroxide yields an intermediate which is again reacted with formaldehyde to form pentaerythritol. An analogous reaction starting with formaldehyde and n-butanaldehyde yields trimethylolpropane. Condensation between formaldehyde and ammonia yields hexamethylenetetramine, and the Reppe reaction yields 1,4-butanediol which is then hydrogenated to yield 1,4-butanediol or 1,4-butanediol [Ex. 73-53]. Methylol formation is probably the most commercially significant formaldehyde reaction since the highly reactive derivatives formed are used as the starting point for resin production [Ex. 73-53].

Uses of Formaldehyde

Formaldehyde has four basic uses: as an intermediate in the production of resins; as an intermediate in the

production of industrial chemicals; as a bactericide or fungicide; and as a component in the formulation of end-use consumer items. The manufacture of three types of resins: urea-formaldehyde, phenol-formaldehyde, and melamine formaldehyde, accounts for about 59 percent of total consumption [Exs. 70-2; 73-52]. An additional seven percent is consumed in the production of thermoplastic acetal resins [Ex. 8]. About one-third is used in the synthesis of high volume chemical derivatives, including pentaerythritol, hexamethylenetetramine, and butanediol [Ex. 8]. Two percent is used in textile treating and small amounts of formaldehyde are present as preservatives or bactericides in consumer and industrial products, such as cosmetics, shampoos, and glues.

Some products prepared from formaldehyde contain unreacted formaldehyde residues or yield formaldehyde upon decomposition. One example is urea-formaldehyde resin. Urea-formaldehyde resin is a generic name that actually represents an entire class of related formulations. A wide variety of resins is produced by polymerizing different ratios of urea and formaldehyde at different pH levels and concentrations. Additives, which consist of thickeners, hardeners, plasticizers, extenders, curing agents, and modifiers, may also be added [Ex. 73-53].

Over 60 percent of urea-formaldehyde resin production in 1977 was consumed by particleboard and plywood manufacturing, where the resin is used as a glue. Urea-formaldehyde resins are also used in decorative laminates, textiles, paper, and foundry sand molds [Ex. 73-53].

Textile treating to impart wrinkle-resistance to clothing is not a major use of formaldehyde on a strict volume basis. However, apparel manufacture is the sixth largest industry sector in the United States [Exs. 70-2; 70-14]. About 60-85 percent of all apparel fabric is finished with formaldehyde-containing resins, and this use is the major source of widespread exposure to formaldehyde because of the large number of workers potentially exposed.

Phenol-formaldehyde resins are produced by condensation of methylol derivatives [Ex. 73-53]. The type of resin formed is controlled by the amount of ring substitution, phenol to formaldehyde ratios, and the catalyst used. They are low-cost binders with many applications, the greatest use being in the formation of wood products, especially softwood plywood [Ex. 73-52]. Phenol-formaldehyde resins are also used in the production of plastic molding

compounds, insulation, foundry molds, and abrasives [Ex. 16].

Polyacetal resins and melamine-formaldehyde resins also have significant uses. Plastic molding compounds are the primary market for melamine formaldehyde resins [Ex. 70-2], and this accounts for the use of formaldehyde in housewares such as plates, cups, and buttons [Ex. 16]; the main use of melamine formaldehyde resins, however, is for decorative laminates used in furniture, countertops, and wall panels [Ex. 73-52]. The properties of polyacetal resins that make them particularly useful include dimensional stability, lubricity, resistance to moisture and organic solvents, and high electrical resistance. End uses include: parts for automobiles, plumbing fixtures, hardware, lawn and garden equipment, and sporting goods.

Acetal thermoplastic resins are used in a wide variety of injection molded parts; about 95 million pounds were sold in 1980 [Ex. 73-52]. These engineering plastics have excellent mechanical and electrical properties, and they are resistant to moisture and solvents [Ex. 73-52].

Formaldehyde is a relatively reactive chemical used as a precursor for the production of other chemicals. These include: pentaerythritol, hexamethylenetetramine, 1,4-butanediol, chelating agents, 4,4'-methylenediphenyl diisocyanate 4,4'-methylenedianiline, pyridine chemicals, trimethylolpropane, and nitroparaffin derivatives, and urea-formaldehyde concentrates (for fertilizers) [Ex. 70-2].

Formaldehyde destroys bacteria, fungi, molds, and yeast. Its commercial importance as a fungicide is probably its greatest use as a disinfectant [Ex. 70-2]. In addition to its use for disinfection in the free state, it is also used in the form of a formaldehyde donor. Examples of uses of formaldehyde for disinfection include: sick rooms, mushroom farms, and poultry hatcheries. Such uses generally come under the jurisdiction of EPA.

Because of its bactericidal properties, formaldehyde is used in numerous cosmetic preparations. The Cosmetic Ingredient Review (CIR) Expert panel examined data submitted to FDA by cosmetic firms in 1981. Formaldehyde preservative was used in 805 formulations. Of the cosmetics examined, 429 contained greater than 0.1 to 1 percent formaldehyde and 366 contained less than 0.1 percent formaldehyde. Two products contained greater than 5 to 10 percent formaldehyde and eight products contained 1 to 5 percent. (It was

impossible to ascertain if concentrations applied to formaldehyde or to formalin, defined as 37% by weight formaldehyde.) Seven of the 10 products with concentrations of 1 percent or more were hair products. There were 475 hair products containing less than 1 percent formaldehyde. Formaldehyde was also contained in viral vaccines, at a level of 0.05 percent, as an inactivating agent [Ex. 42-26].

Formaldehyde's uses can lead to widespread exposure in downstream industries. For example, when formaldehyde is present in disinfectants, preservatives, and embalming fluid, worker exposure can occur. Although formaldehyde changes into other chemicals when urea-formaldehyde resins, urea-formaldehyde concentrates, and hexamethylenetetramine are produced, the reaction is reversible, causing workers in numerous industries, including wood products and apparel manufacture to be exposed to airborne formaldehyde when it offgasses from products. However, other products, such as acetyl resins, pentaerythritol, and butanediol undergo irreversible reaction, so these products release little, if any, formaldehyde.

V. Health Effects

Summary

Workers have developed various health effects from inhalation of airborne formaldehyde and from dermal contact with formaldehyde solutions or products containing formaldehyde. At airborne concentrations as low as 0.1 ppm, formaldehyde causes irritation of the eyes, nose, and throat. As airborne concentrations increase, the severity of the irritation increases, and irritation spreads from the nasal passages and throat into the lower respiratory system. Very severe conditions, e.g. exposures over 50 ppm, have caused severe lacrimation (tearing of the eyes) and pulmonary reactions, including pneumonia, bronchial inflammation, and pulmonary edema [Exs. 42-85, pp. 30-33; 42-87, p. 187]. Massive inhalation of formaldehyde has caused accidental death in humans [Ex. 42-85, p. 76]. A concentration of 100 ppm is "immediately dangerous to life and health" (IDLH) and believed to be a potentially fatal level if exposure continues for 30 minutes or more [Ex. 80-272].

Long-term inhalation of formaldehyde gas is associated with nasal cancer in experimental animals. Some studies in humans exposed to formaldehyde have demonstrated increased nasal and nasopharyngeal cancer. Thus,

formaldehyde should be regarded as an occupational carcinogen.

Skin irritation is a well-known consequence of dermal contact with formaldehyde. Formaldehyde reacts with skin, resulting in a response not unlike the tanning of leather. Employees such as pathologists or undertakers, who handle embalming fluids or other concentrated solutions of formalin frequently showed evidence of skin disease. Dermal contact with formaldehyde-bearing resins have also caused skin disorders (see the NIOSH Health Hazard Evaluations, in Exs. 78 and 85, for example).

Dermal sensitization to formaldehyde is a well-known phenomenon. Among atopic individuals seeking assistance at allergy clinics, formaldehyde is among the top 10 sensitizers found in patch testing results [Ex. 92]. A person sensitized to formaldehyde would have serious difficulties working in industries, such as garment manufacturing or textile finishing where there is repeated dermal contact with sensitizing materials. Sensitization is not readily reversed so a worker may be unable to continue his or her line of work.

OSHA is aware of a few cases where the inhalation of formaldehyde either caused or exacerbated asthma. This phenomenon has been less thoroughly studied than sensory irritation, so that little can be stated about underlying mechanisms of action. In extremely rare cases, inhalation of formaldehyde has caused a dermal reaction [Exs. 42-66; 70-57].

Acute Exposure

Formalin, if ingested, is highly toxic, with an approximate oral lethal dose, the LD₅₀, as low as 50-100 mg/kg, *i.e.*, 1 to 2 tsp for an adult male. The National Academy of Sciences (NAS) reported that accidental or suicidal deaths occurred following ingestion of as little as 30 ml of formalin [Ex. 42-87, p. 199]. There are numerous other case reports where persons who have ingested formalin recovered with medical intervention [Ex. 42-85]. The more concentrated the solution, the greater the damage to the gastrointestinal tract. Damage to the esophagus and stomach has ranged from hardening of the tissue to extreme corrosion, congestion, edema, tissue erosion, and hemorrhage [Ex. 42-85]. Less concentrated solutions are only moderately to very toxic, with oral LD₅₀ doses in man estimated to be a few ounces.

The inhalation of high concentrations of formaldehyde is also extremely dangerous. The IDLH concentration is 100 ppm [Exs. 80-272; 175-20], a level 50

times the STEL being promulgated by this revision. In comparison with the average industrial chemical, the potential for acute toxicity of formaldehyde is quite high, and lethal concentrations could be attained in emergencies or confined spaces in some industry sectors.

Poor work practices, failure of engineering controls, and simple spills can easily result in airborne concentrations in excess of 10 ppm. Such levels have occasionally been measured in OSHA inspections [Exs. 42-95; 42-96; 73-158; 175-17; 175-18]. Concentrations of 5 to 10 ppm can produce cough and a feeling of chest tightness in the exposed worker [Exs. 42-87, p. 194; 77-11] and are extremely irritating to the eyes, resulting in lacrimation and possible ocular damage [Ex. 42-85].

Accidental splash exposures of the human eyes to aqueous formaldehyde solutions have resulted in severe injuries. The severity of effects is concentration dependent and is affected by the speed with which treatment is provided. The NAS reported that immediate flushing saved the eyes of a worker splashed with 40 percent formaldehyde from permanent injury; a similarly exposed worker whose eyes were not flushed lost vision in both eyes [Ex. 42-87, p. 188]. Application of 0.005 ml of 15 percent formalin to rabbit eyes caused a severe reaction, corneal and conjunctival edema and iritis, graded 8 on a 10 point scale [Ex. 42-87, p. 180].

Dermal Effects

In his testimony at the OSHA Hearings, Dr. Edward Emmett, who is a specialist in occupational medicine with a particular interest in skin disease, described the effects of formaldehyde on the skin [Ex. 127]. Additional information on dermatitis, which is discussed in the proposal [50 FR 50427-50430], is incorporated by reference.

The major effects of formaldehyde on the skin are the development of irritant dermatitis and the development of sensitization which leads to allergic contact dermatitis. Formaldehyde may also cause urticaria (hives).

Irritant dermatitis occurs as a result of direct injury to the skin from contact with formalin solution or formaldehyde. This results in redness and thickening of the affected areas. In more severe cases there may be blistering, scaling, and the formation of fissures in the skin. These signs are generally accompanied by burning or itching. When the damaging exposure ceases, irritant reactions usually heal within days or a few weeks at most. After several weeks the skin is

restored to normal. Medical treatment is necessary or desirable to suppress and heal the more severe reactions.

Many factors influence the development of irritant reactions when the skin is exposed to formaldehyde. Irritant reactions are more likely to occur under conditions of low humidity, repeated wetting and drying of the skin, temperature extremes, mechanical trauma (particularly small cuts or abrasions), preexisting skin disease, conditions in which formaldehyde is occluded against the skin so it does not evaporate, and concomitant exposure to other irritating substances. Irritant skin reactions are more prone to occur or to be more persistent in individuals who are atopic, that is those who have suffered one or more of the following: allergic asthma, allergic rhinitis (hay fever), infantile eczema or childhood eczema. About 20–30 percent of the general population is atopic. Although irritant reactions to formaldehyde are fairly common, information on the incidence or prevalence of the condition in the workforce is limited.

Formaldehyde is also a relatively common and important cause of allergic contact dermatitis. This condition is immunologically determined. As a result of skin exposure to formaldehyde, specific allergic sensitization to formaldehyde is induced. This process of induction takes seven to ten days after contact with formaldehyde. Upon subsequent contact, the skin recognizes formaldehyde as foreign and allergic contact dermatitis develops at and around the site of contact. Allergic contact dermatitis is manifested by itching, redness, swelling, multiple small blisters and scaling. It tends to become more severe with repeated exposures to the allergen.

Allergic sensitization usually lasts for life, particularly when the allergen is a commonly used substance such as formaldehyde, which is likely to be recontacted. A sensitized individual will react to a much smaller amount of formaldehyde than is normally necessary to produce skin irritation. Once sensitized to formaldehyde, a person will also react to skin contact with any form of formaldehyde, such as formalin solution, formaldehyde gas, solid polymerized formaldehyde, or formaldehyde released from resins or other compounds.

According to Dr. Emmett, there are currently no data to determine precisely a safe level of dermal contact to formaldehyde for a sensitized individual. However, he cited the experiments of Jordan *et al.* (J. Amer. Acad. Dermatol. 1:44–48, 1979) as showing that the level of formaldehyde

in liquid products must be reduced to about 0.3 percent before they can be tolerated by the majority of formaldehyde-sensitized individuals. Some sensitized individuals reacted at levels even lower than 0.3 percent.

Dr. Emmett pointed out that, while formaldehyde sensitization has been induced experimentally in humans who had repeated contact with 5 percent formalin (2% formaldehyde), the lowest level able to produce sensitization has not been determined. He stated:

In my clinical experience, formaldehyde sensitization of workers in the chemical industry can often be traced to a spill or accidental contamination of the skin with formalin solution. [Ex. 127, p. 9].

Dermatitis Seen in Workers: Even though skin diseases and disorders are the leading cause of lost workdays in the U.S. workforce [Ex. 139A], records regarding causative agents are not generally kept. Diagnoses to determine the nature of the disorder, whether it is an irritant or allergic dermatitis, are also generally not made. Thus, the number of cases of formaldehyde-induced dermatitis and the subset of cases that represent true sensitization to formaldehyde remain unknown.

Formaldehyde, however, is a well-known sensitizer; it accounts for a large number of responses seen in patients at allergy clinics. For example, in 1984, the North American Contact Dermatitis Research Group reported that 376 patients had positive patch-tests to allergens other than "poison ivy", and 52 were due to formaldehyde. Formaldehyde was the fifth most frequent cause of proven contact dermatitis, ranking after poison ivy and nickel and very slightly behind paraphenylenediamine and ethylenediamine [Ex. 127, p. 10].

There have been numerous studies of worker groups and individual case studies indicating that workers who handled formaldehyde solutions or formaldehyde-releasing resins have developed skin diseases and disorders; the percentage of workers affected was often high. For workers handling solutions, formaldehyde was clearly the responsible agent; for workers handling formaldehyde-releasing agents, formaldehyde was suspected of being one of the responsible agents. In both situations workers with skin disorders also frequently complained of irritation of the eyes and respiratory system, characteristics of formaldehyde exposure.

As an example, NIOSH Health Hazard Evaluation Report HETA 83–301–1478 [Ex. 85–24] described an outbreak of dermatitis among employees

of a uniform manufacturer. The major product was firefighter jackets, made from material treated with acetophenone and melamine-formaldehyde resin. In the first two weeks of April 1983, 13 of 102 employees complained to management of symptoms that included rash on the face, neck, arms, and legs; itching; eye and throat irritation; headaches; dizziness; nausea; and sleep disturbance. Of the 13, nine had multiple visits to local physicians for the occurrence of a fine, red, maculopapular rash; three had one visit for the rash; and one experienced a rash but did not see a physician. In five cases, the diagnosis was known to NIOSH from review of the medical records. The rash was described as allergic dermatitis or urticaria.

Personal monitoring of four employees who had experienced symptoms indicated that 8-hour TWA concentrations averaged 0.16 ppm (range 0.15–0.18).

Fabric samples were analyzed for free formaldehyde. Three samples present at the plant contained 300 ppm (*i.e.* 0.03%) (range 100–600 ppm) by weight of formaldehyde. Three samples from the textile mill were measured by a Burlington Industries technique for "latent formaldehyde." They contained 311 ppm (range 260–450) of formaldehyde. After 2.5 months, these samples yielded essentially the same results as before, indicating that residual formaldehyde was still present in the cloth. The supplier analyzed 8 samples using a method intended to provide estimates relevant to airborne levels expected to result when the cloth was used in apparel manufacturing. The 0.19 ppm (range 0.01–0.71) airborne estimate was in agreement with the in-plant measurements.

The NIOSH investigators concluded that airborne levels of formaldehyde of less than 1 ppm and cloth containing less than 750 ppm by weight (0.1% is 1,000 ppm by weight) of formaldehyde were associated with occupational dermatitis among the textile workers. The NIOSH investigators indicated that the textile industry considers a 1 ppm airborne concentration to be the exposure level below which skin sensitization would be prevented [Ex. 85–24, p. 6]. This view was apparently based upon observation that the only source of airborne formaldehyde was the cloth. Thus, the airborne level would roughly approximate the amount of irritating and sensitizing material present in the cloth. The NIOSH study suggested, however, that airborne concentration levels below 0.2 ppm, and

not 1 ppm as cited by industry, might be needed to prevent dermal effects in the apparel industry.

NIOSH made recommendations to limit future outbreaks of dermatitis from melamine formaldehyde treated textiles at the plant [Ex. 85-24]. These recommendations included: obtaining information from textile mills on the concentrations of relevant chemicals in the fabric; periodic airborne sampling to examine possible correlations between content of formaldehyde in the fabric, and employee symptoms; storage of fabric to allow for offgassing of formaldehyde to lessen irritation; use of long-sleeved shirts; and use of fabrics with the lowest concentrations of free formaldehyde compatible with standards of fabric quality and other attributes.

NIOSH also conducted other studies of textiles in relation to occupational dermatitis. In Health Hazard Evaluation Report HETA 83-254-1393 [Ex. 85-23], NIOSH examined three women and a man who were exposed to formaldehyde while working as steam press operators during the post-curing of durable press fabrics.

Overall, the plant employed about 125 persons to manufacture uniforms. Shirt fabrics were precured with a glyoxal-based resin system, dimethylol dihydroxyethylene urea (DMDHEU). Trousers, however, were post-cured by steam pressing and heating in an oven so that the trousers would retain their crease.

Breathing zone formaldehyde exposures for the press operator averaged 0.44 ppm (standard deviation of 0.02) and for the oven operator, they were 0.5 ppm (single sample). Area samples averaged 0.47 ppm (range 0.34-0.53). Four cloth samples being used were mailed to NIOSH to test for formaldehyde. One sample contained 200 ppm of latent formaldehyde by weight using the Burlington method (limit of detection was 150 ppm).

Two of four employees in the post-cure area completed health questionnaires; one reported eye irritation, sore throat, coughing, and skin problems. Out of a total workforce of 125, 64 employees in other areas also participated in the health evaluation. Of these subjects, 44 (69%) had eye irritation, 28 (44%) nose and throat irritation, 24 (30%) headache, 21 (33%) coughing, 15 (32%) sore throat, and 15 (23%) "skin problems." No exposure data were collected for these other workers, who were primarily seamstresses.

In August 1982, NIOSH received a request to investigate an outbreak of skin rash among employees who sewed

shirts from cotton containing a formaldehyde-resin finish [Ex. 85-21]. The NIOSH medical investigators administered a work and medical history and health status questionnaire to randomly selected employees at two plants and to 30 volunteers who had a skin rash. The two plants employed 170 and 130 employees, respectively.

A suede cloth sample was associated with the outbreak of skin rash at one plant. It had a latent formaldehyde content of 421 ppm by weight, 3 to 4 times higher than the other two cloth samples obtained at the plant. Lint samples collected from table surfaces showed nearly identical formaldehyde content to that of cloth material generally in use (138 ppm). NIOSH investigators felt that lint and dust containing formaldehyde could be a significant source of employee exposure.

Over the preceding year, 58 percent of the employees interviewed at one plant and 49 percent at the other indicated that they had developed skin rashes. The employees attributed their problems to material from one textile finishing supplier. This supplier consistently provided cloth with higher formaldehyde levels, about 200 ppm to over 500 ppm by weight, than the other two. Airborne exposures, measured by impinger, solid sorbent, and hand-held monitor ranged from 0.11 to 0.50 ppm at one plant and 0.13 to 0.65 ppm at the other plant. No particular job was associated with higher formaldehyde concentrations, and airborne concentrations appeared to result from the cumulative release of formaldehyde from all operations. There was a general buildup of formaldehyde over the workshift, with morning concentrations being lower than afternoon concentrations.

NIOSH made recommendations to decrease the incidence of dermatitis at the two plants. These were: continued monitoring of formaldehyde content of the cloth; job transfers for sensitized workers; the wearing of long sleeved garments and pants to reduce skin exposure; storage of raw material in isolated areas; and improvement of air quality.

NIOSH has also conducted investigations of dermatitis in apparel manufacturing where the problems were attributed to the textile finish, a glyoxal-based resin, DMDHEU. In a 1977 investigation of a uniform manufacturer (HHE 77-074-720) [Ex. 77-11], 26 of 210 employees (12.4%) were identified as having work-related formaldehyde exposure symptoms. Of these, 15 (7.1%) had skin reactions described as erythematous or urticarial. Airborne sampling showed concentrations of 0.25

ppm (range 0.13 to 0.57). Latent formaldehyde levels in fabrics tested ranged from 850 to 938 ppm by weight. An 86-91 percent reduction in the amount of formaldehyde released was measured after 3 weeks of storage.

In another investigation of a uniform manufacturer, begun in 1982 (HHE 82-200-1233) [Ex. 85-20], 44 of 56 employees had eye irritation, and 18 complained of skin rash, most often of the forearm. NIOSH determined through personal sampling that the average concentration of airborne formaldehyde was 0.26 ppm (range 0.08 to 0.44). Fresh samples of cloth had a latent formaldehyde level of about 334 ppm by weight, and stored samples ranged from 146 to 225 ppm.

A NIOSH investigator summarized the information in the scientific literature [Ex. 85-21], including the HHEs described above. From this information, he concluded that airborne levels of formaldehyde below 1 ppm and as low as 0.08 ppm have been associated with occupational dermatitis. Bulk samples of fabric involved in outbreaks of dermatitis generally had latent formaldehyde levels well below 750 ppm by weight. The determination of latent bulk fabric formaldehyde concentrations provides an indirect indicator of airborne formaldehyde concentrations. However, the two methods do not correlate exactly due to differences in resin formulations, types of fabric, and local environmental conditions.

Occupational dermatitis associated with formaldehyde exposure is not limited to the garment manufacturing industry. In the proposal, OSHA described two studies of embalmers who were reported to have skin problems. Of 57 persons who participated in a survey of funeral homes by Plunkett and Barbela [Ex. 42-101], 37 percent had skin irritation. Two of seven embalmers interviewed by Kerfoot and Mooney [Ex. 73-88D] experienced dermatitis. Other case reports include: a 28-year old man exposed through use of fabric softener [Ex. 73-29]; a 20-year old woman who developed urticaria when exposed to spray starch containing formaldehyde [Ex. 73-33]; an offset-printing machine clerk [Ex. 70-45]; two persons working with newsprint containing resins [Ex. 70-45]; a foundry worker making molds [Ex. 70-45]; renal dialysis workers [Ex. 70-45]; workers in histology and pathology laboratories [Ex. 70-45]; a mushroom farmer using formaldehyde as a disinfectant [Ex. 70-45]; a lithoprinter handling formaldehyde-preserved adhesive [Ex. 70-45]; a case of contact urticaria from formalin-treated leather [Ex. 73-23]; five nurses handling

thermometers immersed in 10 percent formaldehyde [69-8B]; and itching and red spots in 26 of 120 foundry workers [Ex. 73-103].

Of 180 patients, aged 16 to 67, examined by Wallenstein and Rebholf [Ex. 42-123], 12 (6.2%) reacted to formalin (0.07 to 0.3% formaldehyde). These persons had been exposed to formaldehyde in various industries and many also had symptoms of bronchial obstruction and rhinitis.

Dermatitis From Formaldehyde-Bearing Compounds: Pirila and Kilpio [Ex. 73-135] examined 24 cases of occupational dermatitis caused by exposure to formaldehyde solutions or resins. Of these, 20 cases were caused by formalin used as a preservative. Four cases showed sensitization to formaldehyde bearing resins; two also responded to formaldehyde solutions. Five of the 24 workers developed dermatitis which lasted over a year, six were affected 6 to 12 months, 10 for 1 to 6 months, and 3 for less than a month. In this study 17 patients had disabilities severe enough to prevent work; in one for over 18 months, in 6 for 1 to 6 months, and in 10 for less than a month. Nine patients had to change occupation.

Formaldehyde-releasing compounds are widely used as preservatives in industrial and household products, cosmetics, and medicine [Ex. 73-160]. They are formulated by reacting formaldehyde with one or more substituted alkylamines, hydroxy, and mercapto compounds. Andersen *et al.* [Ex. 73-160] used the guinea pig maximization test to examine the sensitizing potential of formalin and six formaldehyde-releasing products used as biocides in water-based metal-working fluids or cosmetics. Formaldehyde sensitized 50 to 95 percent of the guinea pigs and Grotan BK sensitized 20 to 74 percent; corresponding rates were 20 to 25 percent for Forcide 78, KM 200, and Preventol D2, while Germall 115 and Grotan OX sensitized 60 to 70 percent of the animals.

The authors [Ex. 73-160] observed that the relationship between formaldehyde contact allergy and reactions from formaldehyde condensates remains unclear, with neither the guinea pig studies nor human patch test experience giving a clear answer. In humans, 7 of 13 patients sensitive to Grotan BK also reacted to formaldehyde. Four of 678 other allergy clinic patients reacted to Forcide 78, and all were also sensitized to formaldehyde. Thus, "formaldehyde seems to be the common hapten in some cases; in others, sensitization is directed

towards the formaldehyde releaser" [Ex. 73-160, p. 263].

According to Hatch and Maibach [Ex. 85-56], chemicals used in fabrics to improve performance characteristics have resulted in irritant or allergic contact dermatitis; the most significant problem is due to formaldehyde and N-methylol compounds to produce durable press fabrics. Thirty-seven durable press formulation chemicals were tested by Malten (reported in Ex. 85-56) for ability to sensitize. Patch tests were applied to the skin of 66 patients suspected of having textile finish hypersensitivity. Of these, 27 reacted to one or more of the durable press chemicals. The greatest number of reactions followed exposure to uncured N-methylol ingredients, but 7 reacted to formaldehyde.

Andersen and Hamann [Ex. 73-74] found that 15 of 428 patients in a dermatology clinic had eczema due to contact with textile finishing resins. Urea-formaldehyde resin was the main contributor, other formaldehyde resins gave only occasional responses to patch testing. All 15 patients also responded to 2 percent formaldehyde. The 15 patients with dermatitis from textiles constituted 8.6 percent of all patients allergic to formaldehyde who, in turn, constituted 3.7 percent of all patients examined from 1970 to 1980.

In an early study of the role of free formaldehyde in textiles in relation to formalin contact sensitivity, Berrens *et al.* [Ex. 73-96] reported that the free formaldehyde content of most fabrics, was far below the concentration required to give a positive patch test.

The authors nevertheless observed that patients with textile dermatitis obtained relief from symptoms by ceasing to wear clothing with a high level of free formaldehyde. The authors postulated that more formaldehyde than suspected may be released from clothing. For example, the authors suspected that in the armpit area, cloth would liberate more formaldehyde when being worn than it would in their standardized extraction procedure. The authors also postulated that while hydrolysis of the resin on the fabric would split the methylol end groups (releasing formaldehyde), other bonds might also be broken, resulting in the liberation of organic acids and glycine-formaldehyde addition products. This would suggest that persons who exhibit textile dermatitis might be sensitive to the resin formulation, to formaldehyde, or to other chemicals formed from the breakdown of the resin.

In plants where the only source of formaldehyde exposure is from resins used in textile finishing, the airborne

levels of formaldehyde should give an approximate indicator of the risk of sensitization from formaldehyde experienced by workers. This relationship is less than perfect, since environmental factors, *e.g.*, heat, humidity, and air change rates, influence the amount of formaldehyde released from the cloth. Manufacturers' specifications for "free formaldehyde" content in the cloth also provide valuable information to determine when employees might be at greatest risk.

Allergic dermatitis from contact with phenol-formaldehyde resins has been associated primarily with those based on paratertiary-butyl phenol and formaldehyde (PTBP-F-R) [Ex. 73-88]. Of 1,220 patients in two separate studies patch tested with phenol formaldehyde resins, 23 responded to formaldehyde. According to Pirila and Kilpio [Ex. 73-135], finished products which contain phenol-formaldehyde resins should not contain free formaldehyde or phenol, and these products cause dermatoses less frequently than products made from urea-formaldehyde resins which readily release formaldehyde. One case of phenol-formaldehyde induced dermatitis was described in testimony at OSHA's May 1986 hearing. Dr. Daniel Teitlebaum, a clinical toxicologist, described a severe reaction to formaldehyde in a patient who developed edema over his entire skin after his hands had been in contact with phenol-formaldehyde resins [Tr. May 5, 1986, pp. 113-114].

OSHA's Conclusions Regarding Dermatitis: The major effects of formaldehyde on the skin are irritant dermatitis and allergic contact dermatitis. Irritant dermatitis results from a direct injury to the skin and is more prone to occur or persist in atopic individuals, *i.e.* about 20 to 30 percent of the general population. Allergic contact dermatitis, unlike irritant dermatitis, is immunologically mediated. Once a person is sensitized, subsequent contact of the skin with formaldehyde in much smaller amounts will result in a reaction.

According to Imbus [Ex. 68-19], concentrated solutions, probably above 5 percent, produce reddening and inflammation, Pirila and Kilpio [Ex. 73-135, p. 38] noted that "even as a 3-4 percent solution, formalin hardens the epithelial layers of the skin, which becomes dull, rough, and fragile." Hatch and Maibach indicated that 2 percent formalin in water is the best concentration to use for patch testing, except for certain units such as the Finn Chamber, where 1 percent is more appropriate [Ex. 85-56, p. 8]. Patch test

concentrations are intended to elicit a reaction in persons sensitive to formaldehyde without causing an irritant response. In the absence of more definitive data, OSHA used this type of information to establish criteria for circumstances in which the employee's skin would require protection.

Dermal diseases and disorders represent a serious problem in the U.S. workplace, accounting for over a third of all reportable occupational diseases [Ex. 139A]. Formaldehyde is one of the most common causes of occupational skin disease [Ex. 127, p. 10]. Numerous reports of dermatitis in the textile industry indicate that use of formaldehyde-bearing resins is a major source of skin disease in this industry [Exs. 85-23; 85-24; 77-11]. Historically, 8.6 to 65 percent of all formaldehyde sensitive patients also developed allergic textile chemical finish dermatitis [Ex. 85-56, p. 8]. While formaldehyde is not the sole source of irritation and sensitization in textile finishing resins, both tests on free formaldehyde in cloth and airborne concentrations of formaldehyde provide convenient indirect measures of employees' risks of developing skin disease. When particularly irritating materials have been present, levels of airborne formaldehyde and "free formaldehyde" in cloth have both also tended to be higher. Evidence from NIOSH HHEs clearly demonstrates that textile workers remain at risk of developing dermatitis when levels of airborne formaldehyde are well below 1 ppm. At 0.5 ppm, the dermatitis incidence rate was still substantial; at 0.1 ppm, however, the dermatitis risk appeared to be minimal.

Workers in other industries have also developed dermal irritation and sensitization from formaldehyde. A great number of the existing cases have occurred in workers having potential contact with formaldehyde solutions.

Dermatitis From Inhalation of Formaldehyde: Gaseous formaldehyde has been implicated as a cause of allergic skin reaction in sensitized persons. Lesions observed include drying and reddening of the skin of the face, neck, or arms and itching eruptions of the face, neck, arms, or hands [Ex. 69-83]. The classic study of Horsfall [Ex. 42-66] illustrates this phenomenon. A sensitized subject developed vesicles of the skin when given provocative inhalation tests with 10 ppm of formaldehyde. A similar case of urticaria of the face, neck, forearms, and hands occurred in a pathology worker exposed to approximately 1 ppm of

airborne formaldehyde [Ex. 77-19A, Att. 7].

Lee and coworkers [Ex. 70-57] used the guinea pig as an animal model to study sensitization to formaldehyde. The purpose of the study was to identify the route of exposure most likely to cause sensitization and the potency of formaldehyde as a sensitizing chemical. The three routes of exposure employed were inhalation, topical application, and injection. As in the human case reports, the authors were able to induce sensitization in guinea pigs that inhaled formaldehyde.

For inhalation, groups of guinea pigs were exposed to formaldehyde at 6 ppm or 10 ppm for 6 hr/day for 5 days or 10 ppm for 8 hr/day for 5 days. Animals were evaluated for skin sensitivity, production of antiformaldehyde antibody, and respiratory sensitivity (immediate and delayed) to formaldehyde. Two of the four animals in the highest exposure group developed dermal sensitivity, although no antibodies or pulmonary sensitization was observed in any animal.

From this limited information, OSHA concludes that, while allergic skin reaction can result from airborne exposure to formaldehyde, at low doses this reaction probably occurs only in persons who have already been sensitized to formaldehyde. Sensitization of a previously unsensitized person from airborne exposure would not be expected to occur except under extreme conditions, such as in an emergency or an IDLH atmosphere.

Absorption Through the Skin: Jeffcoat [Ex. 69-22A] examined the percutaneous penetration of formaldehyde to determine if formaldehyde released from permanent press clothing would penetrate the skin. The Rhesus monkey was selected for testing because of skin permeability similar to that of humans.

Five monkeys were examined 24 hours after dermal application of 0.4 to 0.9 $\mu\text{g}/\text{cm}^2$ of radiolabeled formaldehyde; 33 percent of the radioactivity was found in the surface layers of the skin at the site of application, 55 percent had evaporated. Only small amounts were recovered in the urine or the breath. Tissues and organs of one monkey necropsied 24 hours after dermal application contained less than 0.2 percent of the applied dose. The author calculated that percutaneous penetration of formaldehyde was 0.27 to 0.46 percent of the applied dose. These amounts were so low that the author could not determine whether penetration was from formaldehyde or from an impurity.

Formaldehyde was used as a control in a study by Robbins and Norred [Exs. 69-13; 73-63] who investigated the dermal penetration and resultant distribution of radioactivity released from fabric patches treated with radiolabeled DMDHEU.

Fabric patches were applied to the clipped backs of New Zealand white rabbits. Another group received occluded patches containing labeled formaldehyde, in aqueous solution, applied to a clipped area on the back. Four hours after application, topically applied formaldehyde was retained on the skin in a percentage of the applied dose that decreased from 72 percent to 58 percent when the applied dose increased from 0.37 to 37 mg. Excretion of radioactive carbon dioxide in the expired air during the 4 hours increased from 1.18 μg after the 0.37 mg topical dose to 98.2 μg after the 37 mg dose. Only small percentages of the applied radioactivity were recovered from the vital organs.

When fabric patches were applied, formaldehyde or some other breakdown product of DMDHEU was found in the skin in measurable quantities. This radioactive material was bound at the site of the patch test and penetrated the dermis poorly.

The uptake of DMDHEU-related products was enhanced by occlusion of the patch and by perspiration, and it was influenced by the manufacturing process used for DMDHEU. Under the most severe conditions, occlusion of the cloth with rubber, 2.5 percent of the radioactivity was transferred from the cloth in 48 hours. Semiocclusion, which is more typical of conditions under which clothing is worn, resulted in about a 10-fold decrease in transfer of radioactivity to the animal.

The CPSC conducted an investigation to determine if radioactivity that penetrates the skin is formaldehyde, an adduct, or a metabolic product [Exs. 73-51; 73-61]. Freshly prepared rabbit skin was placed in a diffusion cell with labeled solutions of formaldehyde in the donor compartment. The radioactivity that passed through to the receptor side (generally below 1%) did not contain any detectable concentration of free formaldehyde. This indicated that any exposure that does occur from the absorption of formaldehyde solutions through the intact skin is to some large molecule that has incorporated formaldehyde.

From these studies, OSHA concludes that systemic absorption of formaldehyde through the intact skin does not constitute a serious risk to persons in the workplace.

Sensory Irritation

In distinguishing various toxic effects, Leidel *et al.* [Ex. 73-176, p. 20] described irritants as corrosive in action. Irritants inflame the moist mucous surface of the body. Airborne concentration is of greater importance than is length of time of exposure. Examples of irritant materials that exert their effects primarily on the upper respiratory tract are aldehydes, alkaline dusts and mists, acid mists, and ammonia.

Clinical Studies of Sensory Irritation: Irritation of the eyes, nose, and throat is an acute response to formaldehyde that diminishes rapidly once the subject is removed from exposure. Because of these properties, sensory irritation has been examined in controlled studies using human volunteers. These studies took place prior to the information regarding carcinogenicity. The advantage offered by such studies is that the exposures can be controlled and measured with great precision and accuracy. The major disadvantage is that healthy, young volunteers may be poor surrogates for the working population, which includes many persons who are older and may have been exposed to formaldehyde for many years.

Several studies described in the preamble to the proposal [50 FR 50421] attempted to define irritant effects in human volunteers. A synopsis of this information is given below.

Bender *et al.* [Ex. 42-15] exposed volunteer subjects to formaldehyde at concentrations of 0.35 to 1.0 ppm for a duration of six minutes. In this short time, 42 percent of the persons exposed at 0.35 ppm experienced "slight eye irritation". At 1 ppm, the symptoms were sufficiently severe to statistically distinguish the exposed group from air-exposed controls.

Rader [Ex. 73-88W] exposed medical students and laboratory employees for 1 hour to formaldehyde at concentrations of 0.1 to 5 ppm. A 1-day period was allotted between exposures to allow for recovery. Subjects ranked six factors: odor perception; eye sensations; irritation in the nose and throat; tearing; and nasal secretion. The number and severity of complaints was related to formaldehyde exposure, and the increase in complaints was significantly greater than background rates at concentrations of 0.2 ppm and above. There was a sharp increase in complaints when concentrations were increased from 1 ppm to 3 ppm.

Rader [Ex. 73-88W] also examined the effects of humidity on the number of complaints recorded at 0.5 ppm. For a 30-minute exposure, total complaints

were significantly more frequent when the chamber air was at 40 percent relative humidity than when it registered 88 percent.

Anderson and Molhave [Ex. 42-10] exposed volunteer students to formaldehyde for 5 hours at 0.3, 0.5, 1.0, and 2.0 mg/m³ (0.24, 0.4, 0.8, and 1.6 ppm). The length of time before the subjects complained of symptoms decreased with increasing dose. At 0.3 and 0.5 mg/m³, no one reported discomfort for the first two hours. At 1.0 and 2.0 mg/m³, subjects reported discomfort within the first hour. At the highest concentration, 2.0 mg/m³, discomfort on the average never exceeded 18 on a scale of 0 to 100. This represented the middle of the range of "slight discomfort". However, at this concentration, the highest individual score reached 50 units, and only 6 of the 16 subjects reported no discomfort (versus 9 at 1.0 and 14 at 0.5 mg/m³). At the conclusion of the exposure, 15 of the 16 subjects, who had been exposed at 1.0 or 2.0 mg/m³, complained of conjunctival irritation and dryness of the nose and throat.

Day and coworkers [Ex. 69-23C2] exposed 18 persons to 1 ppm of formaldehyde for 90 minutes. Fifteen described eye irritation, seven reported nasal congestion, six had tearing of the eyes, five had irritated throats, three had nasal discharge, two had cough, and one had chest tightness.

Schacter [Exs. 73-38; 183] exposed 15 healthy volunteers for 1 hour to 2 ppm of formaldehyde with the subject either at rest or exercising. The subjects reported sore throat, nasal discharge or stuffiness, and eye irritation. In most cases, subjects described their symptoms as mild or moderate, but some reported their symptoms as severe.

Since December 1985, when the proposal was published, one additional study of controlled human exposure, that by Saunders *et al.* [Ex. 138-R], has become available. When these volunteers performed work while they were being exposed to formaldehyde, they had relatively more nose and throat irritation and less eye irritation than previous volunteer studies had found. The authors attributed their findings to increased breathing rates when exercising; this would affect the quantity of formaldehyde inhaled but not the amount reaching the eyes.

Sensory Irritation Reported in Worker Groups: Irritation of the eyes, nose, and throat in workers is most easily detected in cross-sectional studies of actively employed workers and from comparing the results of respiratory disease questionnaires. A major source of information on irritant effects of

formaldehyde resulting from exposure in the workplace is the NIOSH Health Hazard Evaluation (HHE) program. Several reports, outlined below, were described in the proposal. Irritation has often been reported in conjunction with other adverse effects including skin diseases or disorders, pulmonary function shifts, and even changes in the epithelial cells of the nasal passages.

Horvath and associates at the Marshfield Clinic [Exs. 66-5; 80-51] administered respiratory disease questionnaires to 109 employees exposed to formaldehyde resins in particleboard and molded products operations. The control subjects consisted of 254 workers not exposed to formaldehyde.

The questionnaires revealed significant differences between the formaldehyde workers and the control group in a number of complaints. These included itchy and burning eyes, itchy and burning nose, stuffy nose, and sore and burning throat. When test results were segregated into four categories, the authors found a clear dose-response relationship. Exposure category predicted cough, chest discomfort, burning eyes, and sore throat. For example, for burning nose, positive responses were given by 2, 16, 27, and 42 percent in the groups exposed at 0 to 0.04 ppm, 0.04 to 0.4 ppm, 0.4 to 1.0 ppm, and 1.0 to 3 ppm, respectively. Corresponding figures for sore throat were 4, 8, 21, and 32 percent, respectively.

Main and Herman [Ex. 73-32] administered an American Thoracic Society respiratory disease questionnaire to a group of 38 foundry corerom workers. Workers exposed at concentrations above 1 ppm (not exceeding 3.9 ppm) reported a statistically significant increase in frequency of cough compared with a matched group of assembly workers. All corerom workers (exposure range of 0.18 to 3.9 ppm) reported a significantly higher incidence of eye, nose, and throat irritation than did the control group. The irritant effects tended to begin after work started and disappear at the end of the workshift.

Yefremov [Ex. 42-130] reported a study of 278 employees at Russian wood-processing plants. The majority of the workers complained of throat irritation, diminished olfactory sense, and dry nose and pharynx. Airborne formaldehyde concentrations of 2.6 to 11 mg/m³ (2-9 ppm) produced illness in 39.1 to 6.2 percent of those exposed. Airborne formaldehyde concentrations of 0.6 to 4.1 mg/m³ (0.5-3.3 ppm), with a maximum of 8.8 mg/m³ (7.1 ppm),

produced an illness rate of 14.6 to 37.5 percent. When the workers were compared with 200 age-matched controls, the prevalence of symptoms (exposed vs. unexposed) was: chronic laryngitis (0-3.5% vs. 1.5%), and chronic sinusitis (0-4.2% vs. 1.5%). Rhinitis and pharyngitis were more prevalent in workers exposed under 5 years, possibly suggesting that sensitive workers were leaving their jobs.

Workers at an Italian factory producing urea-formaldehyde and melamine-formaldehyde resins were exposed to formaldehyde at 1 to 4 ppm [Ex. 42-100]. Seventeen of 20 workers whose health status was examined had pharyngitis and 12 had conjunctivitis.

In a medical interview with NIOSH, 75 percent of a group of workers who made bags to hold potatoes described symptoms of mucous membrane irritation. Their exposures, measured by NIOSH, were 0.14 to 0.9 ppm [Ex. 78-27].

In another NIOSH study, 15 of 26 textile finishing workers reported eye irritation. In addition, 6 had sinus congestion, 10 had headaches, and two had irritated skin. Exposure measurements conducted by NIOSH revealed concentrations between 0.16 and 1.12 ppm [Ex. 78-24].

Another group of textile workers exposed to formaldehyde-bearing resins who were studied by NIOSH had medical histories revealing eye irritation in 95 percent, nasal irritation in 72 percent, sore throat in 35 percent, and skin effects in 25 percent. These workers were also examined by a physician. On the day of examination, 10 percent had eye irritation, 26 percent had nasal irritation, 2 percent had a sore throat, and 22 percent had skin lesions [Ex. 78-84].

Histopathology technicians at 13 worksites showed a high prevalence of respiratory symptoms and dermatitis [Ex. 78-53]. Of the technicians, 79 percent reported at least one employment-related symptom as compared with 39 percent in a control group. Exposure estimates ranged from 0.2 to 1.9 ppm.

Of 23 medical students studied by NIOSH, 12 showed symptoms indicative of formaldehyde effects. Eight had eye irritation and a dry or irritated throat; six had headache, nasal irritation, dizziness, and cough; and one appeared to be allergic to formaldehyde [Ex. 78-34].

At a hemodialysis unit, NIOSH interviewed 22 nurses exposed to formaldehyde at concentrations of 0.04 to 1.3 ppm. Seven reported no problems, 12 had upper respiratory and eye irritation, and three showed possible

respiratory hypersensitivity. Five had skin problems [Ex. 78-76].

At a college of mortuary sciences, three of four instructors, who had worked with formaldehyde eight to 50 hours a week for 3 weeks to 13 years, reported to NIOSH that they had burning of the eyes and nose, dry mouth and throat, cough, headache, and tearing of the eyes [Ex. 78-20].

Additional NIOSH HHEs forwarded to OSHA since the proposal was published indicate that sensory irritation remains a problem in some industries using formaldehyde. For example, garment industry workers exposed at 0.16 to 1.12 ppm reported eye and respiratory tract irritation [Ex. 85-18].

In another study of garment workers, a steam-press operator complained of headaches, eye irritation, and sore throat. Exposure levels in the area were 0.42 to 0.50 ppm. Sixty-four other employees, mostly seamstresses were interviewed. Eye irritation was reported by 44 (69%), nose and throat irritation by 28 (44%), headache by 24 (38%), coughing by 21 (33%), sore throat by 15 (23%) and skin problems by 15 (23%) [Ex. 85-23].

NIOSH was requested to examine an outbreak of skin rash among employees at two facilities where sheets were sewn from resin-finished cotton materials [Ex. 85-21]. Airborne formaldehyde concentrations averaged 0.3 ppm at plant 1 and 0.5 ppm at plant 2. At plant 1, 89 percent of the employees interviewed reported having experienced burning eyes at some time in the last year, and 72 percent had experienced burning throat, 37 percent chest tightness, and 44 percent skin rashes. At plant 2, corresponding incidences were 100 percent for burning eyes, 46 percent for burning throat, 1.5 percent for chest tightness, and 58 percent for skin rashes.

In another instance, NIOSH found formaldehyde exposure levels of 0.26 ppm (range 0.08-0.44) as 8-hr TWAs and 0.40 ppm (0.32-0.54) as 30 minute samples at a plant sewing work shirts from pre-cut material. Fifty-six female production workers completed a medical questionnaire, and 79 percent reported eye irritation within the last two months. Twenty (36%) had these symptoms more than twice a week. On physical examination, 11 persons (20%) had mild to moderate inflammation of their conjunctiva. Dermatitis was also present. NIOSH concluded that the pattern of eye and skin symptoms was compatible with low-level formaldehyde exposure [Ex. 85-20].

OSHA's Conclusions Regarding Sensory Irritation: The effects of formaldehyde observed in clinical

studies and cross-sectional surveys of workers have been related to the upper respiratory system. In numerous studies, formaldehyde has caused at least one of the following signs or symptoms: burning and itching of the eyes or nose, stuffy nose; and sore or burning throat. For example, complaints were made by employees manufacturing particleboard and molded plastics (27% with nose and 21% with throat irritation at 0.4 to 1.0 ppm), by foundry corerom workers exposed to more than 1 ppm of formaldehyde, by dialysis nurses exposed at 0.26 to 0.4 ppm, by embalmers exposed at 0.25 to 1.39 ppm, by carpenters exposed at 0.36 ppm, by textile finishers exposed at 0.16 to 1.2 ppm, and by garment workers with exposures of 0.42 to 0.50 ppm. Several groups reported headaches related to "stuffy noses" or sinusitis. Two groups [Exs. 42-100 and 42-130], exposed at concentrations probably exceeding 3 ppm on occasions showed evidence of chronic respiratory irritation.

Clinical studies of human volunteers indicate that they become aware of sensory irritation from formaldehyde at concentrations around 1 ppm after exposures of a few minutes. Eye irritation is usually the first effect noticed, followed by irritation of the nose and throat. A 5-hour exposure resulted in sensory irritation at concentrations as low as 0.24 ppm. These volunteers had impaired mucociliary clearance at concentrations of 0.8 ppm and above, a finding duplicated in Yefremov's workers [Ex. 42-130], and potentially indicative of the breakdown of the body's protective mechanisms.

Irritant symptoms are difficult to quantify because the researcher's ability to chronicle them is determined by the ability of the person who experiences them to describe the sensations. Some scientists have expressed the opinion that a quantitative assessment of the risk of irritant effects is not possible [Ex. 70-56]. In addition, a no-effect level [NOEL] that would protect all individuals appears to occur at a concentration of formaldehyde so low that it cannot be measured using currently available sampling procedures. Even exceptionally sensitive individuals, however, exhibit a decrease in severity and number of symptoms as concentrations of formaldehyde decrease.

Asthma

The occupational environment may contribute to the onset of asthma by three mechanisms: (1) It may provoke specific sensitizing agents; (2) it may be

primarily responsible for the development of bronchial hyperactivity; and (3) it may provide symptoms in subjects with pre-existing bronchial hyperactivity [Ex. 85-43].

The most characteristic symptom of occupational asthma is episodic breathlessness related to exposure within the workplace. Symptoms may develop within minutes of exposure (immediate reaction) or several hours after the exposure, either during the latter part of the work day or after returning home (late reaction). The development of asthma may be influenced by whether exposure to the etiologic agent is continuous or intermittent. Exposure to high concentrations for a short period may be more hazardous than exposure to low concentrations over an extended period [Ex. 85-43].

To determine if the asthmatic response is likely to result in progressive deterioration of lung function, pulmonary function tests should be performed repeatedly, both at work and away from work, throughout the day for several weeks. If lung function returns to normal overnight, the peak expiratory flow rate will exhibit a similar decline each workday with full recovery overnight. If the period of recovery is 1 to 3 days, progressive deterioration will occur during the work week with recovery on the weekend. If recovery is longer than 3 days, there will be a progressive deterioration until a new, low, basal level is reached [Ex. 85-43].

Cross-Sectional Studies of Workers: There is sufficient information, as shown below, to conclude that asthma has been induced by exposure to formaldehyde, especially in the presence of particulates. There is, however, insufficient information to determine how quickly lung function recovers, so that it is not clear if a deterioration will occur over time.

In the proposal, several studies showing acute shifts in pulmonary function among workers exposed to formaldehyde were discussed [Exs. 66-5; 73-32; 42-5]. Information updating two of the studies was supplied by Horvath [Ex. 80-51] and by Main, who testified at OSHA's hearings. This information has assisted OSHA in determining if asthmatic responses to formaldehyde are likely to result in progressive deterioration of lung function.

Horvath and coworkers at the Marshfield Clinic [Exs. 66-5; 80-51] assessed acute and chronic effects of formaldehyde in the mucous membranes and lungs of 109 employees exposed to formaldehyde-bearing resins in particleboard and molded products operations. Airborne formaldehyde

levels were 0.17 to 2.93 ppm. Control subjects were 254 workers in other industries with no formaldehyde exposure.

Pre- and post-shift spirometry did not reveal evidence of chronic lung changes. However, dose-dependent, statistically significant post-shift declines in forced expiratory flow (FEF) 25-75%, FEF 50%, and FEF 75% were seen. A subgroup of "reactors" with shifts in FEF 25-75% and ratio of forced expiratory volume in 1 second (FEV₁) to forced vital capacity (FVC) showed dose-dependent post-shift changes, and among these "reactors" those with the most severe responses were more likely to be formaldehyde workers.

Main and Herman [Ex. 73-32; Tr. May 7, 1986] compared the respiratory status of 38 coreroom workers exposed to formaldehyde in a foundry with a matched group of men not exposed to formaldehyde. All were administered pre- and post-shift spirometry and a chest x-ray. The formaldehyde-exposed workers showed dose-dependent decreases in FEV₁, FVC, and FEF 50% over the course of the workshift even though the control group showed increases. There was some indication that lung function had not completely recovered by the beginning of the next workday. The results led the authors to conclude that exposure to formaldehyde at concentrations exceeding 1 ppm causes short term loss of pulmonary function along with symptoms of irritation, which were also observed.

Alexanderson *et al.* [Ex. 42-5] conducted a cross sectional survey of 47 carpenters exposed to formaldehyde for at least one year. On the average, they had been exposed for 5.9 years. The mean concentration of dust in the workplace was 0.5 (0.3-0.7) mg/m³ with mean formaldehyde concentrations of 0.36 (0.04-1.25) mg/m³ (0.3 (0.03-1.0) ppm). Twenty subjects employed at the same facility and not exposed to formaldehyde served as controls.

Pulmonary function tests, including spirometry and single breath nitrogen washout were normal on Monday morning. Statistically significant reductions in maximum midexpiratory flow and significant increases in closing volume as a percent of the vital capacity were found at the end of the workshift. The authors described this lung function change as probably of an obstructive nature, but moderate, and not likely to cause a measurable restriction of physical activities.

Low and Mitchell [Ex. 85-66] reported that 11 of 46 workers exposed to molding fumes and vapors in an Australian steel foundry developed wheeze and other respiratory tract

symptoms. Symptoms were most often reported when workers were exposed to materials used in the Furane process (urea formaldehyde and furfuryl alcohol). Pulmonary function studied over Monday and Friday showed small and inconsistent changes. Pulmonary function recorded before work on Monday showed no evidence of chronic airway obstruction in the foundry workers. The authors believed that both irritant and hypersensitivity mechanisms were involved in producing the workers' symptoms.

Bracken *et al.* [Ex. 104D-3] examined pulmonary function in 10 laboratory technicians and evaluated their workplace exposures to formaldehyde. Spirometric measurements were made on four occasions; immediately before and after work on both Monday and Friday. The mean formaldehyde concentration was 0.12 (0.08-0.44) ppm in the morgue area, 0.27 (0.06-0.40) ppm in the surgical pathology area, 0.12 (0.03-0.28) ppm in the tissue preparation area, and 0.11 (0.02-0.21) ppm in personal samples collected from medical anatomists. There were no significant changes in FVC, FEV₁, FEF₂₅₋₇₅ although one worker, a smoker with a family history of asthma, had a abnormal baseline FEF₂₅₋₇₅ and the greatest decline in FEV₁ over the course of the workweek.

Levine *et al.* [Ex. 42-73], in 1984, examined the respiratory status of morticians who were attending a postgraduate course in West Virginia. The investigators found no evidence of chronic bronchitis and concluded that "long-term intermittent exposure to low levels of formaldehyde gas exerts no meaningful chronic effect on respiratory health." Since the morticians had been unexposed for several days before the spirometry was conducted, the study screened out any possible influence from acute effects, which may account for the differences seen in this study as compared with the foundry workers [Ex. 73-32] and particleboard workers [Ex. 80-51].

Measurements conducted at six funeral homes for Levine's study revealed mean TWA concentrations (averaged only over the time of actual exposure) of 0.3 ppm (range 0.2-0.4) for intact bodies and 0.9 ppm (range 0.5-1.2) for autopsied bodies. The 30-minute exposures were 0.4 and 2.1 ppm, respectively [Ex. 42-128].

Stenzel and Harris [Ex. 72-3] compiled medical monitoring results from employees exposed to formaldehyde at the Celanese production plant in Bishop, Texas. Their intent was to determine if any changes in pulmonary function

related to formaldehyde exposure occurred over periods of 6 months or three years.

A total of 971 employees, with an average age of 40.3 years and duration of employment of 12.7 years, were included in the study. Exposure concentrations were 0 to 2 ppm, but employees exposed at concentrations exceeding a 1 ppm TWA wore respirators. There was no trend between duration of exposure and lowering of FVC, FVC%, FEV₁, FEV₁% and ratio of FEV₁/FVC. There were also no trends with increasing exposure.

Schoenberg and Mitchell administered respiratory disease questionnaires and spirometry to employees exposed to phenol-formaldehyde resin [Ex. 42-106]. Although acute changes in lung function were small, there was a tendency for pulmonary function to decrease over the workshift and over the workweek, suggesting the possibility of chronic lung function shifts. Fifteen men who worked on the production line for more than 5 years had reduced FEF₅₀ and FEV₁ / FVC% [Ex. 42-106]. Those working on the production line had intermediate values between the long-term workers and unexposed controls. Exposures ranged between 0.4 and 0.8 ppm (when ventilation functioned), based on indicator tube measurements, which may not be reliable.

Results from the respiratory disease questionnaires showed wheezing, chest tightness, and shortness of breath (possible signs of asthma) in 38 to 45 percent of the exposed workers as compared with 12 to 25 percent in those previously exposed, and 5 to 7 percent in those never exposed.

Pisanti *et al.* [Ex. 42-100] also found evidence of respiratory sensitization in 4 of 40 workers in a small factory that made urea and melamine resins. Although none continued to work directly with formaldehyde, two of the four had both pruritis (itching) and bronchial asthma, one had bronchial asthma, and one had pruritis.

A survey of 80 embalmers in 20 Los Angeles funeral homes revealed that 37 percent had skin irritation, 23 percent had chest tightness, 10 percent had shortness of breath, 33 percent had cough, and 12 percent had wheezing. Of the 80 respondents, nine had symptoms indicative of acute bronchitis and 17 had chronic bronchitis [Ex. 42-101].

These latter studies, unlike the reports by Levine *et al.*, Bracken, and Celanese, indicate that chronic bronchitis and asthma can result from formaldehyde exposure, at least under circumstances where exposures are quite high according to current standards.

Case Reports: Case studies of several investigators have described acute and chronic bronchitis [Ex. 12-101] and asthma or sinus problems and dermatitis among embalmers [Exs. 73-88D; 78-26]; respiratory allergy in a medical student [Ex. 78-32]; respiratory hypersensitivity and skin problems in hemodialysis nurses [Ex. 78-76]; allergic rhinitis and asthma in a spray painter and a chemical factory worker [Ex. 42-2] and carpenters [Ex. 73-88X]; and possible occupational asthma that had forced retirement in a mortuary school instructor [Ex. 78-20] and a pathologist [Tr. May 5, 1986, pp. 110-111]. Occupational asthma in workers exposed to urea-formaldehyde resin fumes was also attributed to formaldehyde [Ex. 73-88L]. It is likely that these persons had been exposed to formaldehyde at concentrations over 1 ppm at least some of the time.

One of the most frequently cited case reports of respiratory sensitization is the study of Hendrick and coworkers [Ex. 42-62]. Eight of 28 renal dialysis nurses who had exposure to formaldehyde developed asthma or bronchitis. Two of these nurses experienced wheezing, a sensation of tightness in the chest, and cough with symptoms worsening at night. They also had hematological changes including eosinophilia; provocative inhalation tests induced the asthmatic symptoms.

Hendrick and associates [Ex. 42-63] retested the two asthmatic dialysis nurses. When first tested, in 1973 and 1975, they developed bronchoconstriction at 2 and 10 hours after receiving 3 or 5 ppm of formaldehyde in inhalation provocation tests. When retested in 1981, the nurse who had ceased working in the renal dialysis unit in 1976, 3 years after her first test, did not respond to challenge with 6 ppm of formaldehyde. The other nurse continued to work in the dialysis unit, and the experienced repeated mild attacks of asthma, usually related to formaldehyde spills. When exposed to a challenge concentration of 3 ppm as in 1975, her bronchoconstrictive response was about one-half as severe as before.

Clinical Studies of Asthma: At the time the proposal was published, several clinical studies of the role of formaldehyde in inducing asthmatic symptoms had been published [Exs. 70-46; 73-16]. Since then, additional studies [Exs. 73-179; 138R] have been instrumental in providing explanations for the differences seen in these controlled clinical tests, where asthma was not seen, and in workers, where acute pulmonary function shifts have been evident in persons exposed at

concentrations probably exceeding 1 ppm.

Frigas and coworkers [Ex. 73-16] studied 11 women and two men with a history of asthma and exposure to formaldehyde gas. In seven cases, these exposures had been measured; they ranged from 0.1 to 1.2 ppm. All reported symptoms they attributed to formaldehyde: chest tightness, coughing or wheezing, nasal congestion, irritation of the eyes, and headache.

Each patient, while asymptomatic, underwent bronchial challenge for 20 minutes with room air and at least one of three concentrations of formaldehyde: 0.1, 1, and 3 ppm. Spirometry was performed before the challenge; at 0, 15, and 30 minutes; and at 1, 3, 6, and 24 hours. Where any test induced a 20 percent or greater decrease in FEV₁ in a dose related fashion, the placebo produced the same effect. This led the authors to conclude that they were unable to demonstrate that inhaled formaldehyde caused or aggravated asthmatic symptoms.

Sheppard and colleagues [Ex. 70-46] found no evidence that inhalation of formaldehyde caused bronchoconstriction in asthmatics. Formaldehyde was administered for 10 minutes by mouthpiece under the following conditions: 1 ppm, subject at rest; 1 ppm, subject exercising; and 3 ppm, subject exercising. All seven persons they examined had a history of recurring episodes of wheezing, chest tightness, reversible airways obstruction, and allergic rhinitis. All were hyperresponsive to histamine.

Burge and coworkers [Ex. 73-179] conducted bronchial provocation tests in 15 workers who had been occupationally exposed to formaldehyde. Three workers; a 62-year old plastics molder, a 29-year old printer, and a 59-year old process worker who manufactured phenol formaldehyde, had what the authors described as "classical occupational asthma caused by formaldehyde fumes." These three subjects had appreciable late asthmatic reactions after formaldehyde exposure. Four other workers developed appreciable immediate asthmatic reactions, as did two of the three with late reactions.

The authors [Ex. 73-179] noted that bronchoconstriction induced by forced expiration was a particular feature in immediate reactions to formaldehyde, and responses closely paralleled histamine reactivity. These features appeared to the authors compatible with a conclusion that formaldehyde was acting as a non-specific irritant.

All three persons with severe histamine reactivity had an immediate reaction to formaldehyde when exposed at 3.2 ppm. Two of these responded to concentrations of formaldehyde as low as 0.3 ppm. Exposure at 1.5 ppm failed to induce asthma in one worker with severe histamine reactivity, which the authors [Ex. 73-179] noted was in line with the asthmatic patients studied by Frigas [Ex. 73-16].

Saunders *et al.* [Ex. 138-R] evaluated the symptoms and acute pulmonary response of nine healthy nonsmokers exposed to formaldehyde in an exposure chamber at 3 ppm for 3 hours. The use of an inhalation chamber was intended to overcome possible methodologic problems in the experiments of Frigas *et al.* [Ex. 73-16] and Sheppard *et al.* [Ex. 70-46]. (The authors felt that the face mask used by Frigas may have caused delivery of a lower dose to the person than reported and that the Sheppard study was limited in its ability to simulate exposure because inhalation was through a mouthpiece.)

The nine subjects selected for study were screened to assure that they were healthy. All had normal pulmonary function and all responded normally to bronchial provocation with methacholine. Thus, none had asthma and, in general, they were healthier than the general population or the nonselected workforce.

Each subject served as his or her own control by being exposed in the chamber to clean air for three hours before being exposed to formaldehyde. Spirometric measurements were performed every half hour after exposure commenced. An 8-minute bicycle ergometer exercise was completed 2 minutes prior to each spirometric measurement except at $t=0$.

Even though pulmonary function and airway reactivity to methacholine were normal, significant changes were observed in FEV₁ and FEF₂₅₋₇₅ after 30 minutes of exposure to formaldehyde. No significant changes were observed in FVC at any time, and the other effects became nonsignificant after 30 minutes. The authors [Ex. 138 R] described the pulmonary function decrements as small and not expected to result in a discernible decrease in physical capacity.

Between January 1977 and May 1983, Nordman *et al.* [Ex. 104-E1] examined 230 persons who had been exposed to formaldehyde and suffered from asthma-like respiratory symptoms. Clinical examinations included detailed medical and occupational histories, skin prick tests with common allergens, recording of diurnal variations of pulmonary function, spirometry with a bronchodilation test, a histamine

provocation test, bronchial challenge with formaldehyde, and serologic tests including eosinophil count and total serum IgE. On the basis of medical and occupational histories, the authors concluded that 12 patients had specific sensitization to formaldehyde. These persons had been exposed at work between 1 month and 19 years before onset of symptoms. Eleven of the 12 showed an asthmatic reaction when exposed by bronchial provocation to 2 ppm of formaldehyde, and one responded at 1 ppm.

Seventy-one of 218 persons reacted to histamine in bronchial provocation testing, even though they did not respond to formaldehyde. This would indicate that these persons had hyperreactive airways. The authors [Ex. 104-E1] felt, however, that simply having hyperreactive airways would not preclude diagnosis of formaldehyde asthma because hyperreactivity can be a secondary response to sensitization to formaldehyde as it is in other forms of extrinsic asthma.

OSHA's Conclusions Regarding Asthma: Information from case studies, worker surveillance, and human volunteers is sufficient to conclude that formaldehyde either causes asthma or exacerbates preexisting conditions. The most convincing information is the consistency in which groups of workers have shown across-shift changes in pulmonary function. However, this information is insufficient to determine whether or not a gradual loss in lung function will occur following years of exposure. Some studies point to a progressive shift with time; others show recovery after the workday has ended. Confounding factors, such as exposure to particulates or to other sensitizers could influence the results, but it is OSHA's judgment based on the available evidence that asthma will not be a problem if worker exposure is kept to TWAs at or below 1 ppm.

Case studies of persons who reported wheezing sometimes refer to virtually irreversible effects that did not resolve completely years after exposure ceased, suggesting a true immunologic response. Some reactions were so severe that the individual had to cease working with formaldehyde. The types of the work performed by many of the sensitized individuals, evidence that a single exposure to highly irritating materials can produce asthma [Exs. 85-43; 126, p. 1; Tr. May 5, 1986, pp. 132-133], and evidence that this has occurred in the case of formaldehyde [Ex. 73-175] suggest that it may be especially important to protect workers exposed to formaldehyde in an accident since

asthma can be a serious and potentially life-threatening disease.

Reproductive Effects

In the proposal, OSHA stated that there appeared to be little, if any, risk of reproductive or teratogenic effects from the levels of exposure to formaldehyde typical of the occupational environment. These conclusions were made after careful review of reports by Olsen and Dossing [Ex. 42-98] and Shumilina [Ex. 42-108] which have been cited as evidence that formaldehyde may have caused menstrual disorders in some female workers [Ex. 13]. A deficit in symptoms in control groups appeared to OSHA a more likely explanation for the results than a true adverse reaction to formaldehyde. The report of Hemminki and coworkers [Ex. 42-61] found no evidence of any increase in spontaneous abortions in nurses exposed to formaldehyde even though this same study showed an increase in nurses exposed to ethylene oxide.

In addition to the above-mentioned literature on human reproductive effects, OSHA has also reviewed studies of animal reproductive effects. Marks and coworkers [Ex. 42-78] conducted a study in mice where pregnant mice were intubated with 74 to 185 mg/kg of formaldehyde each day on days 6 to 15 of gestation. No adverse reproductive outcomes were observed. OSHA placed great reliance on this study in determining, for the proposal, that formaldehyde did not induce reproductive effects.

Since the proposal was prepared, Martin described an inhalation teratogenicity study of formaldehyde in Sprague Dawley rats conducted by the Formaldehyde Council of Canada [Ex. 139-A, Att. 2]. Groups of 25 pregnant female rats were exposed to formaldehyde at concentrations of 1.88, 4.88, and 9.45 ppm from days 6 through 15 of gestation. Control animals were either handled identically or maintained in the room. Animals exposed at 9.45 ppm gained significantly less weight than the other animals, but the authors thought this was probably because of decreased food intake. The authors conducted gross pathological examinations and found no treatment related effects. They also examined pregnancy rate, mean numbers of corpora lutea, implants, live fetuses, number of resorptions, and mean fetal weights and found no effects attributable to formaldehyde. In fetuses, there was no evidence of major malformations. Among many potential skeletal anomalies examined, the only difference seen was slightly reduced

ossification of the pubic and ischeal bones in the 4.88 and 9.45 ppm exposure groups. The authors attributed these skeletal findings to larger litter size and slightly lower fetal weights and not to formaldehyde.

This study in conjunction with the oral study in mice and the human studies leads OSHA to conclude that there is no evidence at this time that formaldehyde demonstrates teratogenic effects at exposure concentrations which comply with the revised standard.

Cancer Epidemiology

Introduction: In the preamble to the proposed rule, OSHA examined epidemiologic evidence on formaldehyde and concluded that the human data, taken alone, were insufficient to determine the risk of cancer to workers posed by exposure to formaldehyde [50 FR 50447].

Since that time, several studies associating formaldehyde exposure with an increased risk of cancer have been published. These consist of a standardized mortality ratio (SMR) study of garment workers presented by NIOSH at OSHA's formaldehyde hearings; a large SMR study conducted at the NCI (the Blair *et al.* study) [Exs. 156-A4; 138-T]; interpretations of Blair's data by Sielken [Exs. 104-F; 101-F1; 134], Park [Exs. 108-D; 146-B; 146-D], Blair *et al.* [Ex. 200-4], and Sterling and Weinkam [Ex. 200-1], and new or updated case control studies by Vaughan *et al.* [Exs. 201-3A; 201-3B], Hayes *et al.* [Ex. 173], and Olsen *et al.* [Ex. 201-11A]. The new studies are described below along with pertinent information from studies already described in the preamble to the proposed rule. Various studies have reported an excess of leukemia and cancer of the nasal cavity, nasopharynx, buccal cavity, lung, skin, brain, and prostate. Some of these sites appear more biologically plausible than others based on evidence from animal studies.

Only selected information cited in the proposal are reproduced in this preamble. For a more complete discussion of studies which predate the proposal, see 50 FR 50437-50447, (December 10, 1985), which is hereby incorporated by reference.

Epidemiologic studies consider the relationships of various factors which determine the frequency and distribution of disease. A truly "negative" epidemiologic study, as compared to a "nonpositive" study, must be capable of detecting small increases in risk and it must be well-documented that the cohort had substantial exposure to the potential agent. The study of a small number of

workers that does not demonstrate a significant excess of cancer is uninformative because it is capable of identifying only a very large relative risk of disease. An insensitive study with crude design or crude measuring methods is also uninformative. What determines "large" versus "small" is the size of the study population, the length of follow-up time, and the frequency with which the disease under study arises [Ex. 105-A, Att. IV].

Researchers choose between the different types of epidemiological studies based on their perceived strengths and weaknesses and on what the researcher seeks to learn. For example, a case-control study attempts to discover significant differences between persons who have a particular type of cancer and a matched control group. This type of analysis is often used to confirm suspected causes of cancer. One of the problems with this approach is that cancer registries, which are the principle source of the data used for case-control studies, do not provide exposure measurements. Thus, a dose-response relationship can only be inferred from such studies.

A proportionate mortality ratio (PMR) study examines deaths that have occurred in a population to determine if the proportion of any cause of death is different than expected as compared to proportional mortality in the standard population. The PMR study is more limited than the cohort mortality study because each proportional excess of deaths must be matched by a corresponding proportional deficit by definition in order for the total mortality to equal one. PMR studies are generally conducted because they are less expensive and time consuming than a cohort mortality study.

A cohort mortality study can overcome some limitations of PMR and case-control studies since it examines death rates of in-plant populations and compares them to the rates experienced by a standard population. Variables such as age, sex, race and calendar time period and, ideally, smoking are taken into account so that the study population is similar to the standard or comparison population in all respects that would affect death rates. The scientific and administrative process of identifying a more valid reference group than the general population, which is usually used in cohort studies, would be resource intensive and would make the investigation much more costly. Cohort studies that use the general population as the reference group, however, may tend to underestimate the observed risk of certain diseases because of the "healthy worker effect".

According to Hernberg [Ex. 105-A, Att. IV, p. 124]:

Perhaps the most serious comparison invalidity arises when the general population is used as the reference category. This * * * practice is mainly caused by economic necessity, since the * * * "healthy worker effect" is by now so well known to all epidemiologists that everybody tries to avoid it * * * (It should be stressed that the bias introduced is almost always one that hides existing differences * * * Hence the "healthy worker effect" poses a serious methodological problem whenever occupational groups are compared with the general population.

A cohort mortality study may be incapable of detecting even moderate increases in rare cancers. For example, based on the results of the CIIT and NYU studies, investigators have been concerned that formaldehyde might cause nasal cancer in humans. Yet, the Blair *et al.* study, by far the largest cohort mortality study of formaldehyde workers, had only a 26 percent probability of detecting a relative risk of 2 (twice the risk of the general population) for nasal cancer [Ex. 80-64, p. 10].

It was pointed out to OSHA that the incidence of overall and specific-site cancer fails to show consistent increases from study to study [Ex. 80-64, p. 14]. This apparent inconsistency among studies is as expected because many of the studies in the rulemaking record do not have sufficient power to detect anything less than a large increase in the relative risk of site-specific cancers. The power of a study has to do with its ability to detect an increased risk of disease, if, in fact, one is present. In order to have sufficient power, a study should have an 80% chance of detecting a 50% increase (a relative risk of 1.5 which equals an SMR of 150) of site-specific cancers. Therefore, one would not expect to observe a statistically significant increase in risk of nasal cancer in the PMR or cohort mortality studies reported to date because the sizes of the study populations are not large enough.

Large cohort mortality studies are the preferred method to determine etiology for lung cancer in the occupational setting. Lung cancer is the most common cancer in the U.S. male population and the lung is a suspected target organ for formaldehyde in humans. Of the approximately 30 studies available, only the Blair *et al.* [Ex. 156 A-4] and Acheson *et al.* [Ex. 42-1] cohort mortality studies contained sufficient power to detect low relative risks of lung cancer.

OSHA did not expect that all the epidemiological studies of formaldehyde workers would show an elevated cancer risk. Indeed, OMB has pointed out [Ex. 80-256] that many of the available epidemiologic studies involve workers whose exposure was low, probably never reaching 1 ppm. As explained in more detail in the Risk Assessment section, OSHA predicts very few cancers in workers exposed to formaldehyde at concentrations below 1 ppm.

Epidemiologic studies of formaldehyde also differed substantially in important characteristics which may have influenced their results. For example, Dr. Schneiderman [Tr. May 7, 1986, pp. 47-50] pointed out that "professional" workers exposed to formaldehyde were consistently older than the industrial workers studied.

With regard to statistical analysis of the data, there is an element of choice between the 1-sided and 2-sided test to determine if perceived excesses are statistically significant. Various authors used different techniques to determine statistical significance. In borderline cases, the choice of test sometimes influenced the determination of whether or not a particular excess of cancer was statistically significant [Exs. 118; 139, pp. 60-61; 144; Tr. May 12, 1986, p. 56].

The use of 1-sided versus 2-sided statistical tests remains a debated issue in epidemiologic research [Exs. 100, pp. 72-73; 144-A, p. 4]. Several participants in this rulemaking presented their views regarding the relative merits of the two approaches [Ex. 174, p. 1; Tr. May 8, 1986, pp. 319-320].

OSHA believes that rigid adherence to a distinction between "significant" and "nonsignificant" is inappropriate [Ex. 152-B] because the effect of changing the criteria used to judge the significance of study results is small. Instead, OSHA has carefully weighed the overall evidence, both human and animal, to make a determination regarding formaldehyde's ability to cause cancer in humans. Recalculation of confidence intervals for each study to present them in a uniform manner would not change OSHA's overall conclusions regarding formaldehyde, and thus, OSHA has not performed such recalculations to analyze the epidemiologic evidence.

Nasal Cancer: Because formaldehyde is present in resins used to manufacture wood products, formaldehyde exposure frequently occurs in conjunction with wood dust exposure. The presence of wood dust complicates analysis of data on formaldehyde as a potential nasal carcinogen. Two recent studies examined the risk of different histologic

types of nasal cancer associated with formaldehyde exposure. These studies have helped to clarify formaldehyde's role in the induction of nasal cancer.

Hayes *et al.* [Ex. 173] conducted a case-control study of men who attended hospitals in the Netherlands for surgical and radiation treatment between 1978 and 1981. There were 116 men, aged 35 to 79, with histologically confirmed primary epithelial cancer of the nasal cavities or accessory sinuses. At the study's beginning, 74 were alive and 42 had died. Of these men, 58 percent had squamous cell carcinomas, 24 percent had adenocarcinomas, and 18 percent had tumors of other types, mostly undifferentiated.

For each case, two living controls ($n=223$) were selected by random sampling of municipal resident records and one deceased control ($n=36$) was selected from 1980 death records. Living cases and controls or next of kin were interviewed regarding work history for all jobs held 6 months or more. Information about environmental conditions, workplace exposures to other substances, and tobacco and alcohol use was also solicited. Among those alive, 86 percent of the cases and 77 percent of the controls participated. Next-of-kin interviews were obtained for 64 percent of both cases and controls who were dead. Jobs identified in the interviews were classified by use of the Standard Industrial Classification Manual.

Two industrial hygienists independently evaluated job histories to classify each job according to probability of formaldehyde exposure (Assessments A and B). Wood dust² exposure was coded by one industrial hygienist. Subjects were categorized according to the highest exposure job held and by their probability of exposure to formaldehyde while employed in that job.

There were differences in the classifications of the two industrial hygienists. Of the 286 cases and controls, 65 were considered by Assessment A and 125 by Assessment B to have had at least some potential occupational exposure to formaldehyde. Both industrial hygienists estimated that employees in the following industries had potential exposure to formaldehyde and low exposure to wood dust: agriculture, paper, wood product sales, non-carpentry construction, metals, painting, textiles, chemicals, and electronics. Assessment B also predicted potential formaldehyde exposures in the leather finishing and printing and

graphics industries. In addition, Assessments A and B agreed that employees in the following industries would have both moderate or high levels of wood dust exposure and potential formaldehyde exposure: furniture and cabinet making, carpentry, construction, wood products fabrication and repair, and shoe production and repair.

More controls than cases were exposed to wood dust, causing the authors to express concern that their findings might underestimate the role of formaldehyde in the etiology of nasal cancer. There were no differences in educational levels for cases and controls, but more controls were married and proportionately more cases were over 70 years of age.

The age-adjusted relative risk (RR) for nasal cancer associated with formaldehyde exposure was 2.5 (90% CI=1.5-4.3) using Assessment A and 1.9 (90% CI=1.2-3.0) using Assessment B. (Confidence intervals with lower limits over 1.0 are statistically significant.) Although cigarette use has been associated with a moderate elevation in risk of nasal cancer, adjustment of RR for smoking did not alter the significance of the findings for formaldehyde. Alcohol consumption was not related to nasal sinus cancer. The relative risk for adenocarcinoma was 11.3 (90% CI=4.0-35.1) for workers who had ever been employed in the wood and paper industry, but the risk for squamous cell carcinomas was not elevated for these workers, indicating that it was possible to distinguish between the effects of formaldehyde and "wood dust" exposure.

Therefore, the authors evaluated formaldehyde's effects in the 224 workers who did not have "substantial" exposure to wood dust. Of these men, 15 (Assessment A) to 30 percent (Assessment B) had potential occupational exposure to formaldehyde. For these persons, the RR of nasal cancer was 2.5 (1.2-5.0) by Assessment A and 1.6 (0.9-2.8) by Assessment B. An exposure-related trend was found; for persons with the greatest likelihood of formaldehyde exposure, Assessment B yielded a RR of 2.1 (1.1-4.1).

To further minimize potential confounding effects from wood dust, the authors examined histologic types of nasal cancer. The relative risk (RR) of developing squamous cell, carcinoma of the nasal cavity (a cell type not usually associated with wood dust exposure) in the group with little or no wood dust exposure by Assessment A was 3.0 (1.3-6.4). By Assessment B, RR was 1.9 (1.0-3.6), and estimates using both

² Mention of "wood dust" does not constitute a policy statement on the part of OSHA.

classification schemes showed a dose-response gradient.

Among the 28 cases with the greatest exposure to wood dust, 19 (64%) had adenocarcinomas. Because of the very strong relationship between wood dust exposure and nasal adenocarcinoma, the authors could not assess any possible independent influence of formaldehyde on risks of developing a nasal adenocarcinoma.

The authors [Ex. 173] felt their findings showed that formaldehyde may be a human carcinogen at concentrations found in the recent past in the occupational setting. Hayes *et al.* felt the following points supported the validity of the perceived association: specificity for squamous cell carcinoma which was consistent with experimental data in rodents; a dose response relationship; positive association with nasal cancer from two independent estimates of formaldehyde exposure; and the inability to account for the results by age, alcohol use, wood-dust exposure, or smoking history.

OSHA notes that using either of the independent assessments of formaldehyde exposure potential in cases and controls supports a conclusion that there may be a causal association between nasal cancer and formaldehyde exposure. Indeed, the Agency finds the absence of squamous cell carcinoma among wood-dust exposed workers and the presence of such tumors among formaldehyde-exposed workers to be highly suggestive of an independent role for formaldehyde in the induction of squamous cell carcinomas of the nasal cavity.

Olsen and coworkers [Exs. 73-36; 201-11A] conducted a case-control study of 759 histologically verified cancers of the nasal cavity (287 cases), paranasal sinuses (179 cases), and nasopharynx (293 cases) and 2,465 cancer controls diagnosed in Denmark between 1970 and 1982. Information on job history was derived from a national data linkage system. Two industrial hygienists, who were not informed of whether an individual was a case or a control, examined each person's job history to determine potential exposure to formaldehyde and 11 other compounds or procedures. Of the controls, 4.2 percent of the men and 0.1 percent of the women were exposed to formaldehyde.

A statistically significant excess risk for carcinoma of the nasal cavity and sinuses among men with former exposure to formaldehyde (RR=2.8), wood dust (RR=2.5), and paint, lacquer, and glue (RR=2.1) was found. When adjustment was made for wood-dust exposure, the relative risk associated with formaldehyde was reduced to 1.6,

which was not statistically significant "although still compatible with a 3-4 fold increase in risk" [Ex. 73-36].

In a follow-up study, Olsen and coworkers [Ex. 201-11A] examined the role of occupational exposures on the risk of developing nasal cancers of specific histological type. Squamous cell carcinomas accounted for 72 percent of the tumors, 8 percent were adenocarcinomas, and 20 percent had other origins. For men who developed squamous cell carcinoma following occupational exposure to formaldehyde, RR was 2.3; for those who had been exposed to wood dust, RR was 1.3. The RR associated with exposure to either formaldehyde or wood dust was 1.6, indicating that the two substances acted independently of each other in the development of squamous cell carcinoma. The introduction of a 10-year latency period did not substantially alter the risk estimates.

For adenocarcinomas, a RR of 16.3 was associated with wood dust exposure adjusted for formaldehyde. The RR was 2.2 for formaldehyde exposure adjusted for wood dust exposure and 39.5 for combined exposure, indicating a synergism between the two substances with respect to adenocarcinoma formation.

The elevated risks of 2.3 (ever vs. never exposed to formaldehyde) and 2.4 (10-yr latency) for squamous cell carcinomas were based on 13 and 8 cases, respectively. According to the authors:

These risk estimates for squamous cell carcinomas do not reach a level of significance but are remarkably near the risk estimates found by Hayes *et al.* for squamous cell carcinoma of the nasal cavities after occupational exposure to formaldehyde.

Olsen *et al.* [Ex. 201-11A] concluded: "an independent risk of occupational formaldehyde exposure on the development of both squamous cell carcinomas and adenocarcinomas was * * * indicated by the present study" and that "an interaction of wood dust and formaldehyde seems to exist on the formation of adenocarcinomas of the nasal cavity."

The authors had originally concluded that the joint action of exposure to wood-dust and formaldehyde was in accordance with an additive effect [Ex. 73-36]. In contrast, two witnesses at the OSHA hearings, Drs. Schneiderman and Perera pointed out that the study results, not corrected for histological type, were more compatible with an explanation that the effect was synergistic, or multiplicative [Ex. 96, p. 8; Tr. May 15, 1986, pp. 118-119].

A study of Swedish workers by Malker *et al.* [Ex. 138-I] provides evidence consistent with a slightly elevated risk of nasal cancer in formaldehyde-exposed workers. These investigators used national registries to link nasal cancer incidence from 1961-1979 to census data on industry and occupation. The authors' intent was to assess nasal cancers by histologic type and occupation. By far the greatest risk occurred in furniture industry employees who developed adenocarcinoma (standardized incidence rate (SIR) of 16.7). There was also an approximate 2-fold risk for squamous cell carcinoma in both men and women employed in the textile industry. The study did not provide sufficient data to evaluate the role of formaldehyde exposure in the elevated risk of nasal adenocarcinoma in the furniture industry nor in the elevated risk of nasal squamous cell carcinoma in the textile industry.

The studies described above regarding formaldehyde and human nasal cancer show a remarkable consistency with the rodent data on formaldehyde, which is discussed later (see section on animal carcinogenicity). While the risk of adenocarcinoma of the nasal passages was primarily associated with wood dust exposure, the risk increased in the presence of formaldehyde. The Hayes *et al.* and Olsen *et al.* studies also showed a consistent 2-fold relative risk of squamous cell carcinoma of the nasal cavity for formaldehyde exposure alone. The Olsen study further suggests that formaldehyde interacts with wood dust to produce a RR of 40 for adenocarcinoma in contrast to a RR of 16 for wood dust alone. Such synergistic interaction between formaldehyde and wood dust in the development of nasal adenocarcinoma suggests that over 50% of the nasal cancer in workers with these combined exposures could be eliminated by eliminating or substantially reducing the formaldehyde exposure. The observation of an elevated risk of squamous cell carcinoma related to formaldehyde exposure alone in two separate studies of the nasal passages lends credibility to the use of rat data for human risk assessment.

Lung Cancer—the NCI Study: Shortly after OSHA published its formaldehyde proposal, Dr. Aaron Blair announced the results of a mortality study of workers exposed to formaldehyde. This study was undertaken by the National Cancer Institute (NCI) in collaboration with the Formaldehyde Institute (FI). Dr. Blair acted as principal investigator; his staff, contractors, and members of the Health

Research Committee of the FI assisted Dr. Blair and were credited as coauthors. The report, "Mortality Among Industrial Workers Exposed to Formaldehyde" was published in the *Journal of the National Cancer Institute* in June 1986 [Ex. 156-A4].

The Blair *et al.* study represents the largest cohort mortality analysis conducted of formaldehyde workers. Plants were selected from a pool of 200 companies that produced or used formaldehyde [Exs. 138-T (also 156-A5); 156-A4]. These companies were identified by the FI and other trade organizations, and from directories of chemical producers and users and "other sources." To be eligible for inclusion in the study, a plant had to have necessary personnel records and workers first exposed to formaldehyde before 1966. These qualifications reduced the number of plants to 80. Final selection reduced the number of plants to 10.

The Blair *et al.* study developed over a period of time in response to the CIIT finding of nasal cancer in rats exposed to formaldehyde. The FI developed a preliminary assessment of plants [Exs. 67; 164-F]. Having determined that producers and resin manufacturers, for example, had adequate information for an epidemiologic study, the FI brought this information to the attention of NCI. Dr. Blair, an epidemiologist in the Occupational Studies Section, became interested in the project. He obtained approval for the study from the National Cancer Advisory Board [Ex. 67]. The FI encouraged its members to cooperate in the study [Ex. 158, p. 48 (published version)] and two coauthors representing the Health Research Committee of the FI were employed by companies with plants being studied.

Information regarding plant identity [Ex. 200-13], exposure data collected for the study [Exs. 138-T; 138-W; 138-X], and other exposure and economic data available to OSHA (see the Regulatory Impact Analysis), indicate that the plants selected for study were large. Requirements regarding availability of records and the investigators' attempt to select plants with employee exposure monitoring data probably made a bias toward selection of large plants inevitable.

Workers employed at 4 of the 10 plants selected by Blair *et al.* had been studied, at least in part, by other researchers. This is an extremely high representation; except for the studies of Stayner and coworkers at NIOSH, it includes all U.S. industrial groups exposed to formaldehyde whose mortality experience had been examined previously. This practice was

strongly criticized at NCI oversight hearings because it appeared that the authors had prior knowledge that the plant populations they were selecting for study were unlikely to demonstrate any large cancer risk [Ex. 158-B]. Inclusion of workers from previously studied plants is questionable except where a study is being conducted simply to confirm previous results.

The cohort consisted of 26,561 workers, all employed at the selected plants before January 1, 1966 [Ex. 156-A4]. Subjects were traced until January 1, 1980, to determine vital status. Thus, the study had a minimum follow-up period since first exposure to formaldehyde of 14 years.

For deceased workers, the investigators obtained death certificates. From the death certificates, a nosologist determined underlying causes of death as coded by the Eighth Revision of the International Classification of Diseases. Social Security Quarterly Earnings reports were examined to ascertain the completeness of the cohort. The investigators found incomplete records for plant five before 1957 and plant six before 1951 and adjusted their cohort accordingly to exclude workers employed at these two plants before the dates in question.

Historical exposures to formaldehyde were estimated for each unique job title, work area, and calendar year combination [Exs. 156-A4; 156-A5]. First, some 300,000 job titles from company records were standardized to 6,700 titles. For each plant, job-title, work-area, and calendar year exposure matrices were developed based on company monitoring data, plant operations and changes in these operations over time, and interviews with experienced company personnel. For each job, industrial hygienists developed an exposure profile that contained the following information: estimated 8-hour TWA exposure to formaldehyde; frequency and level of peak exposures (defined as an excursion of short duration, generally less than 15 minutes, that exceeded the upper level of the TWA category assigned); potential for other chemical exposures or exposure to formaldehyde in liquid or solid form; personal protective equipment (PPE) in use; and confidence in the exposure estimates. The assigned rankings for TWA exposure estimates were: (1) Work in a plant in the study, but no known formaldehyde exposure; (2) less than 0.1 ppm; (3) 0.1 to less than 0.5 ppm; (4) 0.5 to less than 2.0 ppm; and (5) greater than or equal to 2.0 ppm.

Second, a listing of all jobs rank-ordered by relative level of formaldehyde exposure was sent to

participating plants for review by their industrial hygienists.

Third, monitoring of existing exposures was conducted during the summer and winter of 1983-84 by use of the DuPont and 3-M passive dosimeter badges and the NIOSH chromatropic acid-liquid impinger method.

Stewart *et al.* explained the methodology of the NCI study in an exposure-analysis paper [Exs. 138-T, 156-A5] which stated:

Although historical exposure estimates cannot be absolutely validated, the comparison of results from the three independent lines of evidence provided a measure of reliability.

The investigators compared the mortality of formaldehyde-exposed workers with that of the U.S. population, the local population, and non-exposed workers [Ex. 156-A4]. Person-years accumulated in the cohort began on January 1 of the initial year of cohort identification, *i.e.* when the individual formaldehyde facility opened, upon employment at the plant for subsequent new hires, or upon the subject's first achieving a specified level or type of formaldehyde exposure. Person-years ceased accumulating at the close of the study period, at the last date known alive or at the date of death.

Expected numbers of deaths were calculated by applying 5-year age and calendar-time period mortality rates according to race and sex. For the 10 counties where the plants were located, local mortality rates were obtained and used for calculating expected deaths. (See Ex. 200-13 which gives the location of each plant and the Atlas of Cancer Mortality for U.S. Counties: 1950-1969 by Mason, McKay, and Hoover.)

Standardized mortality ratios (SMR) were evaluated in relation to formaldehyde exposure using several measures of dose: intensity, represented by the midpoint of the ranking (1 to 5) that encompassed the 8-hour TWA estimate for the job; duration, which was the time period spent in jobs where there was formaldehyde exposure; cumulative exposure, calculated by multiplying the time spent in each job by the midpoint of the ranking assigned to that job; average exposure, which was cumulative exposure divided by time spent in formaldehyde exposed jobs; and peak exposure, defined as the highest exposure ranking experienced whether as a TWA or as a peak excursion above the TWA rank. The effect of exposure to particles and the effect of excluding recent exposures from the exposure index were also examined.

For each measure of exposure, the SMR was calculated for less than 10 years, 10 to 19 years, and greater than 20 years since first exposure. Analyses were performed for each plant and for groupings of plants producing similar products.

Of the 26,561 persons included in the study, 20,714 were white men. About 5 percent of the cohort was lost to followup. Of 4,396 subjects reported deceased, death certificates were found for 92 percent. Approximately 600,000 person-years at risk were accumulated. Of the 24,717 persons successfully traced, 11 percent were unexposed (rank 1), 12 percent had their highest TWA exposure in rank 2 (<0.1 ppm), 34 percent in rank 3 (0.1 to <0.5 ppm TWA), 40 percent in rank 4 (0.5 to <2 ppm TWA), and 4 percent in rank 5 (2 ppm or more).

SMRs were calculated for persons who ever held a job with a TWA exposure estimate greater than 0.1 ppm. Among white men exposed to formaldehyde, SMRs exceeded 100 for leukemia and Hodgkin's disease, cancers of the buccal cavity and pharynx, liver, larynx, lung, bone, skin, prostate gland, bladder, kidney, and eye.

For subsites of the buccal cavity and pharynx, there was cancer of the lip (observed (O)=2, expected (E)=0.6), tongue (O=2, E=5.6), and other parts of the mouth (O=2, E=1.6); nasopharynx (O=7, E=2.2, statistically significant); oropharynx (O=5, E=2.9); hypopharynx (O=2, E=1.9); and unspecified sites (O=1, E=4.4).

Relative risks (RR) of death observed for selected forms of cancer were similar whether cumulative exposure or intensity was used as measures of exposure [Ex. 156-A4]. Prostate cancer and Hodgkins disease showed a dose-response relationship, based on cumulative exposure. Risk of lung cancer was greater in each exposure category than among the unexposed, but the authors saw no rising trend of lung cancer risk with increasing cumulative exposure. The authors also found no trend based on duration of exposure since the SMR for the 20-year latency group was 130 for less than 1 year of exposure, 103 for 1 to 9 years, 157 for 10 to 19 years, and 106 for greater than or equal to 20 years.

Considered in terms of exposure intensity, lung cancer rates among formaldehyde exposed workers as compared to rates for non-formaldehyde exposed workers at the same facilities were elevated in all but, the highest formaldehyde exposure category with a RR of 166 for <0.1 ppm, 159 for 0.1 to 0.4 ppm, 178 for 0.5 to 1.9 ppm, and 79 for 2 ppm or more. Corresponding SMRs for

lung cancer were 60 (no exposure); 110 (<0.1 ppm); 106 (0.1 to 0.4 ppm); 119 (0.5 to 1.9 ppm), and 55 (2 ppm or more).

A similar evaluation to determine the lung cancer SMR for the greater than 20-year latency group produced the following results [Ex. 156 A-4]: in the 0 ppm-yr group, O=5, E=5 deaths; in the less than 0.5 ppm-year group, O=49, E=36 deaths for a statistically significant SMR of 135; and in the 0.5 to 5.5 ppm-yr group, an SMR of 135 (O=53, E=39), which was also statistically significant. For exposures over 5.5 ppm-yr, the SMR was 132, (O=42, E=33 deaths).

Based on the above analysis, Blair and his coinvestigators concluded that:

These data provide little evidence that mortality from cancer is associated with formaldehyde exposure at levels experienced by workers in this study [Ex. 156A-4, p. 1071].

Dr. Philip Landrigan, an epidemiologist who submitted comments and testified on behalf of the American Public Health Association, disagreed with the premise that the presence of rising trends for lung cancer risk and cumulative exposure was required to establish a finding that formaldehyde workers were at an increased risk of lung cancer [Tr. May 9, 1986]. He based his determination on the evidence that there was a statistically significant excess of lung cancer in workers who had a latency of at least 20 years. These criticisms of Dr. Blair's conclusion regarding lung cancer risk were echoed by other parties to the rulemaking [Exs. 96; 98; 146-E].

Dr. Schneiderman criticized Blair's inclusion of workers in the "unexposed" group when they had formaldehyde exposures less than 0.1 ppm because important differences may have been obscured as a consequence. Persons with no exposure to formaldehyde had an SMR of 68 for lung cancer, but those exposed to less than 0.1 ppm had a corresponding SMR of 110. Using this information, Schneiderman calculated that the RR of lung cancer associated with any exposure to formaldehyde was 1.68 [Ex. 96, pp. 12-13].

On April 2, 1986, five members of the Advisory Panel for the study sent a letter to Dr. Blair [Ex. 146-E] expressing their disagreement with the authors' conclusions and objecting to the exclusion of their views from the published report [Ex. 146-E]. These Advisory Panel members stated:

We believe that this study does not resolve the overall issue of whether formaldehyde is a human carcinogen under conditions which existed for the exposed members of the cohort. The finding of a significant increase in the risk for lung cancer (for exposed hourly

workers who were first exposed more than 20 years before their deaths) makes us particularly hesitant to characterize this as a study with little evidence to exonerate formaldehyde as a carcinogen.

NIOSH summarized its position on the Blair *et al.* study and on the accompanying industrial hygiene paper in an evaluation dated June 19, 1986 [Ex. 144-A]. NIOSH stated:

The methodologies used in both studies were sound. Sufficient evidence exists in the Blair *et al.* epidemiologic study to conclude that there are significant excesses of lung cancer in formaldehyde-exposed workers with more than 20 years since initial exposure and of nasopharyngeal cancers in formaldehyde-exposed workers. The absence of an exposure-response trend is not sufficient cause to discount the observed lung cancer excesses, especially given the weaknesses in estimating historical exposures (p. 1).

NIOSH also disagreed with Blair *et al.*'s interpretation of the data based on the absence of a consistent exposure-response trend. According to NIOSH [Ex. 144-A, pp. 10-11]:

Such an interpretation is inadvisable based on epidemiologic studies in general, and this study in particular. First, the position presented by Monson would disagree with the conclusion . . . Monson states that: (1) a dose-response relationship is relatively strong evidence of causality, and (2) the lack of a dose-response relationship is fairly weak evidence against causality due to factors such as exposure misclassification, biases in the measure of exposure, and a non-linear relationship between exposure and the condition.

Dr. Schneiderman pointed out that Blair *et al.*'s analysis implies that cumulative dose is related to duration of exposure and length of follow-up. Dr. Schneiderman noted that this is probably an inappropriate measure for evaluating the possible dose-response phenomena for formaldehyde [Ex. 96, pp. 13-14].

Dr. Schneiderman examined the effect of classifying employee exposure based on an employee's highest exposure job and retaining the employee in that class for duration of follow-up [Ex. 96]. According to Dr. Schneiderman:

This should have the effect of overestimating exposure and underestimating dose-response effects, if there are any. If the over-estimation is "dose" related, then this could suppress appearance of a true dose-response effect.

Thus, Blair *et al.*'s study's methodological problems as well as its assumptions regarding the nature of cancer's progression might account for the failure to find a dose-response relationship, i.e., an increased risk of lung cancer with increased

formaldehyde exposure, better than the conclusion that there is "little evidence" of formaldehyde carcinogenicity. Indeed, the authors' conclusions expressed in the original paper appear very weak given the excesses of cancer consistently found at various sites.

Much of the testimony received by OSHA regarding the Blair *et al.* study is critical of the exposure assessment.

NIOSH [Ex. 144-A] criticized the investigators' approach to estimating exposure because they did not provide supporting data or explanations:

Information on how historical exposure estimates were derived and how historical plant data, historical exposure estimates, and actual exposure estimates were integrated is lacking even though this information is the foundation of the exposure classification strategy.

Concerning the exposure data, Dr. Raphael Moure, an industrial hygienist with the UAW, testified that:

The UAW believes that the narrow range of exposure in the plants selected for the study and the absence of reliable quantitative industrial hygiene data make it impossible to have confidence in the exposure classification effort. The heavy reliance on subjective judgments, which was forced on the investigators by the nature of the data available, precluded evaluations of precision necessary to support conclusions about an exposure gradient and a cancer effect. Methodological errors in this subjective process further eroded the reliability of the results [Ex. 146-A, p. 2].

Dr. Moure criticized the exposure estimates as resulting in "misclassification due to subjective assignment of numerical exposure levels" because there were few exposure monitoring results available from company records. Moure also noted that much of the information consisted of detector tube data and area sampling not relatable to breathing zone exposure.

In a paper by Stewart *et al.* providing details of the study's exposure assessment [Exs. 138-T; 156-A5], the authors stated that:

Most jobs had never been monitored and few sample results were generally available for those that had. Background information on the sampling and analytical protocol was often missing or incomplete.

This statement led Moure to conclude [Ex. 146-A, p. 5]:

Since most jobs were not monitored, it is fair to say that the majority of exposure estimates came from guesses, educated guesses but guesses nevertheless.

Employee exposure was considered to change each time engineering controls were installed or changes in processes took place [Ex. 138-T]. Of the 6,700 job

titles, there were 3,000 modifications made to the exposure estimates as the result of engineering controls or process modifications. Each exposure adjustment was either 33 or 115 percent depending on the judgment of the industrial hygienist.

NIOSH [Ex. 144-A] and the UAW [Tr. May 8, 1986] criticized the way the investigators adjusted exposure estimates to take into account changes in engineering controls and processes. NIOSH stated that it was impossible to substantiate assumptions regarding the effects of process and plant changes from the information provided. The UAW characterized the approach as "guessing at numerical levels" [Ex. 146-A].

OSHA agrees that the failure to establish criteria to evaluate exposure data is a serious limitation in dose-response analyses. Errors of an unrepeatable nature could have entered into the exposure assessment; it is impossible to judge their severity, how frequently they might have occurred, or the extent to which the exposure profiles of individuals could have been affected.

OSHA's Integrated Management Data System (IMIS) data reveal that detector tubes can indicate high readings when specific measurement for formaldehyde shows little or no formaldehyde present. Area samples also can show results higher than personnel samples because workers tend to stay out of irritating "high exposure" areas as much as possible. To the extent that these overall observations are also true for the Blair *et al.* data, exposure estimates determined by different methods of measurement could result in an unsystematic bias for workers comprising the cohort and would have a potentially obscuring effect on any actual dose-response relationship.

OSHA notes that Blair *et al.* have expressed little confidence in their exposure estimates. For example, the investigators indicated that of 2,596 exposures ranked as being over 2 ppm, they were not confident of the assignment in 88.3 percent of the cases [Ex. 146-F]. For 33 percent of the jobs, the investigators had either no confidence or unknown confidence in the level of exposure assigned [Ex. 146-A]. Furthermore, the problem appears to be plant-specific, and it occurs most frequently in long term workers and in those most heavily exposed. If employees were assigned to improper exposure categories as a result, a tendency to obscure any exposure-response relationship would inevitably occur.

NIOSH noted that, while Stewart *et al.* had trouble estimating the higher exposures experienced by long term workers, the cohort's overall formaldehyde exposure was apparently quite low. Indeed, 48 percent of the cohort was classified as having exposures at or below 0.1 ppm, well below either the old standard or this revision. Based on this exposure profile, NIOSH felt that the ability of the study to clearly detect the effects of formaldehyde was very limited [Ex. 144].

Hernberg described, in general, the results of including trivially exposed persons in a cohort mortality study and the effects of exposure misclassification [Ex. 105 A, Att. IV, p. 123]. Hernberg stated:

All too often workers with too short an exposure time and too low an exposure intensity, or sometimes even nonexposed, misclassified workers, are forced into the exposed cohort * * * this practice usually yields quite the opposite of what the investigator (probably) intended. In other words, the study becomes diluted * * * The only justification for such a procedure is the study of the exposure-response relationship, and this, of course, is important information provided the qualitative aspects of causation are already known. But basing a qualitative negative conclusion only on the outcome of subjects with very low exposure intensity and/or short exposure time is unjustifiable.

Thus, exposure classification errors and the inclusion of many persons having minimal exposure, as described above, would bias the Blair *et al.* study toward a failure to find a dose-response and toward underestimation of risk.

In the exposure evaluation, the investigators attempted to standardize historical exposures by collecting 1,667 samples from 261 job titles [Ex. 156-A5]. The investigators claimed a rate of agreement between current sampling and historical estimates of more than 70 percent [Ex. 138-T]. The UAW [Ex. 146-A, p. 10.] and NIOSH [Ex. 144] questioned this assertion since only 10 percent of the 241 jobs for which actual exposure measurements were taken agreed with historical estimates. NIOSH elaborated on how this finding would affect the overall analysis:

For 35 percent of the subset of 261 jobs measured, historical exposure estimates were changed, undoubtedly improving the estimates but also suggesting that there is substantial likelihood for misclassification of exposure for the over 6,400 job titles where no comparison of original estimates to current sampling results were made.

NIOSH concluded that the formaldehyde exposure of the workers covered by the NCI study was low and poorly documented and that the

researchers used an exposure classification scheme likely to assign jobs incorrectly. Therefore, NIOSH stated that it was inappropriate for Blair *et al.* to discount significant cancer excesses on the basis that NCI had not detected a consistent dose-response relationship [Ex. 144]. OSHA agrees with NIOSH since the lack of correlation between actual and historical measurements and use of poor quality monitoring data [Tr. March 7, 1986, pp. 18-21] virtually ensures that some worker exposure was randomly misclassified.

Random errors in exposure classification, like the systematic errors described earlier, do not create nonexistent relationships; they obscure existing exposure response relationships. Poor analytical precision, especially of the determinant variable (in this case, exposure), will decrease existing group differences and level off the regression slope in exposure response studies [Ex. 105-A, Att. IV].

Other Analyses of the NCI Data: Several additional analyses, described below, have assisted OSHA in coming to its conclusions regarding the findings of the Blair *et al.* study [Ex. 156-A4].

At the UAW's request, Blair calculated lung cancer rates for white male workers based on average formaldehyde exposure and national lung cancer rates [Ex. 146-H]. Five categories (<0.05 ppm, 0.05 to <0.25 ppm, 0.25 to <0.5 ppm, 0.5 to <1.50 ppm, and 1.50 ppm or more) for three latencies (<10 yr, 10-19 yrs, and 19 yrs or more) were included. The data suggest a potential trend for lung cancer. For those who received average exposures below 0.25 ppm, the SMR is 98 (O=68, E=69.5) as compared to an SMR of 133 (O=108, E=81.5) for those who had exposures to formaldehyde greater than 0.25 ppm. The trend in lung cancer is similar if the data are dicotomized for those workers who experienced TWA exposures below 0.5 ppm versus those exposed at concentrations greater than 0.5 ppm.

Sterling and Weinkam [Ex. 200-1] were concerned that Blair's emphasis on the failure to find dose response relationships and the potential for the "healthy worker effect" would mask cancer risks from exposure to formaldehyde. To address these concerns, they performed a regression analysis on data from the original study.

Sterling and Weinkam [Ex. 200-1] established four criteria for determining whether or not a job in the Blair *et al.* study should be considered a salaried or a wage position. For each worker, job position in the 5 years immediately before the close of the study period was

not included because recent exposure was deemed irrelevant to expression of cancer. The authors were concerned that workers who had spent significant time in potentially more exposed hourly positions not be classified as salaried. Thus, a salaried worker had to be employed in "salaried" jobs for at least 80 percent of their relevant employment. These alterations changed classifications used by Blair *et al.*, primarily causing a net shift of 1,153 out of 3,388 salaried workers in a total population of 19,925 white men.

Sterling and Weinkam [Ex. 200-1] used a regression analysis, fitting a log-linear model to the number of deaths from all causes, all cancers, and lung cancer. Variables examined included length of employment, average exposure (defined as the integrated exposure over the observation period divided by length of employment) job type and age. Because of the small number of lung cancer deaths, 238 in white males, the authors limited comparisons to two categories for each variable even though this approach limited information generated on exposure-response.

As expected, age (below 60 years and up) was a significant variable in predicting deaths from all causes, all cancer, and lung cancer. The likelihood of dying from any cause or from any cancer was also dependent on whether a worker was listed on the wage or salary role. Average exposure (less than 0.5 or 0.5 ppm and up) showed no correlation with deaths from all causes. Average exposure, however, was a significant predictor of risk of dying from any form of cancer and of lung cancer for both white men and for black and white men combined. There were too few black men in the study to conduct a separate analysis for them.

When the relative risk of death from lung cancer was assumed to be 1.0 for salaried white and black men less than 60 years old, the relative risk of lung cancer for hourly white and black men younger than 60 years was 6.48. The relative risk of lung cancer for black and white men over 60 was 43 for salaried workers and 62 for hourly workers. Results for white men were nearly identical to those with race combined.

The authors concluded that the Blair *et al.* cohort had a significantly increased risk of lung cancer associated with increased average exposure to formaldehyde. They also noted that a consistent difference in relative risk for lung cancer, all cancers, and all causes of death existed between hourly and salaried personnel.

Sterling and Weinkam also demonstrated a significant elevated RR (1.39) for lung cancer among workers

(races combined) who experienced average exposures equal to or greater than 0.5 ppm as compared to those exposed to less than 0.5 ppm. Sterling and Weinkam [Ex. 200-1] analyzed the data for hourly employees only and also found a significantly elevated relative risk of death from lung cancer for those categorized as having average formaldehyde exposures equal to or greater than 0.5 ppm as compared to those having exposures less than 0.5 ppm. The authors stated that Blair *et al.* also found a significant increase in lung cancer related to average exposures [Ex. 99, Table 7].

Sterling and Weinkam [Ex. 200-1] examined the interaction between job type and age with respect to lung cancer risk. The risk for hourly employees relative to salaried employees was 6.48:1 for persons under 60, but it was only 1.44:1 for those who were older. This finding suggested that lung cancers were appearing at an earlier age in wage workers than in salaried employees. The authors observed that this difference "is consistent with the hypothesis that the increase in relative risk for lung cancer is of occupational origin."

To permit comparison of Blair's calculations with those of Sterling and Weinkam, OSHA combined the data in Ex. 146-N to evaluate the lung cancer risk for white male workers exposed at or above 0.5 ppm and for those workers exposed below 0.5 ppm. SMRs were 125 (O/E=100/80.1) and 97.4 (O/E=150/154), respectively. For exposures less than 0.25 ppm versus exposures greater than or equal to 0.25 ppm, SMRs were 81.9 versus 126, also indicating a dose gradient by level of formaldehyde exposure.

The FI commented that "Dr. Sterling's finding of lung cancer excess in the NCI study is entitled to no credibility" because of the failure to correct for cigarette smoking; incorrect and simplistic calculation of person-years of exposure; and the use of only two age groups to examine age effects; insistence on a "healthy worker" effect; and simplistic, incomplete, and selective classification of salaried and hourly workers [Ex. 201-8, pp. 5-23].

While there are limitations inherent in the data as pointed out by Sterling and Weinkam, OSHA is of the opinion that the authors made reasonable assumptions. It is true that adjustments were not made for cigarette smoking, but the same problems were true of the Blair *et al.* study whose conclusions the FI accepts. Whenever information on smoking history is unavailable, use of a comparison group of other workers from the same factories, as was done by

Sterling and Weinkam, is about the best analysis that can be performed to take smoking into account. While Sterling's analysis could have been strengthened by looking at several comparison groups and reducing the data to only two groups if it became necessary, the use of only two groups is not a reason to reject the study. Given the ability of industrial hygienists to distinguish exposures over the very limited range represented by Blair *et al.*'s study, the use of two comparison groups is warranted. In contrast to the FI position, OSHA believes that both the Blair *et al.* analysis and the Sterling and Weinkam analysis are reasonable, and both analyses have been useful to OSHA's interpretation of the data.

Dupont [Ex. 201-13, p. 4] criticized Sterling and Weinkam for failing to adjust for changes in lung cancer rates that have occurred in the general population. Dupont stated:

Sterling and Weinkam do not adjust for calendar year in their reanalysis. This is perhaps the most serious deficiency in their reanalysis, especially in the case of lung cancer, where mortality has changed considerably over time. The lack of any adjustment for calendar year in a study in which risk of dying spans over 40 years would seriously impair the credibility of their reanalysis.

This criticism was echoed by the FI which commented:

Sterling's reanalysis ignores the increased rate of lung cancer in the general population since World War II principally as the result of smoking. Sterling's failure to make this correction for time trends in respiratory cancer casts doubt on the validity of his observations of increased risk, given that lung cancer has doubled in the U.S. over the past 40 years. NCI took into account changes in lung cancer over time, as must be done in any well-conducted lung cancer study analysis [Ex. 201.8, pp. 5-6].

Clearly, cohort mortality studies must take factors such as age and year of death into account since these factors determine expected mortality rates. However, it is naive to presume that all analyses must apply this information in the same manner as the cohort analysis.

Even with regression analysis, in some circumstances the lack of adjustment for time period in which death occurred could confound analysis. Errors would be introduced if the distribution of year-of-death differed substantially between the exposed and the unexposed persons. Sterling indicated, however, [Ex. 205-2], that 88 percent of the deaths in the group with average exposures below 0.5 ppm were between 1965 and 1979, and about 90 percent of the deaths in those exposed over 0.5 ppm also occurred between

1965 and 1979. Forty-two and 45 percent, respectively, died between 1975 and 1979.

Dr. Robert Sielken obtained the raw data used in the Blair *et al.* study from the NCI. From this information he calculated average lifetime exposure, in ppm, for each white male worker ($n=19,927$) [Exs. 104-F; 104 F1; 134]. The exposure estimate took into account all years of each person's life, not just working years, because Dr. Sielken believed that, otherwise, the data would give undue weight to brief but high exposures.

Sielken compared the formaldehyde exposure data with the likelihood of dying from cancer of the respiratory system and lung cancer [Ex. 134]. Data on lifetime average exposure for each individual were aggregated into the following groups: 0 to 0.0001 ppm, 0.0001 to 0.01 ppm, 0.01 to 0.05 ppm, and 0.05 ppm increments thereafter. The percent of workers dying from lung or respiratory cancer for each exposure group was then calculated. Each calculation was repeated assuming latency periods of 1, 2, 5, 10, 15, and 20 years, *i.e.* with the relevant last years of exposure not included in the calculation of exposure. Because each latency period calculation handled a worker's lifetime exposure differently, the number of workers assigned to each exposure group differed for each calculation. For example, 1,590 men were assigned to the lowest exposure category for zero years of latency, but this figure jumped to 7,251 for 20 years of latency.

Sielken applied Armitage's test for linear trend to the resultant data sets and reported that there was no statistically significant trend in any case. Least squares estimates showed a decreasing trend, which was statistically significant for latency periods of 15 and 20 years for both respiratory system and lung cancer as causes of death.

Sielken used two approaches to evaluate the data. In one case, computations were based on all workers. In the other, computations were based on those who had died. Sielken did not take into account either year of death or age at death, two omissions that were criticized by FI reviewers as "serious flaws" in a similar analysis by Sterling and Weinkam.

OSHA further explored Sielken's data on white men who had died, since this information corresponded most closely with reanalyses by Sterling and Weinkam and by Mr. Robert Park, a UAW epidemiologist. Because few persons were exposed above an average daily dose of 0.2 ppm, OSHA aggregated the exposed workers, as classified by

Sielken, into three groups: those exposed over 0.01 ppm, those exposed over 0.05 ppm, and those exposed over 0.1 ppm. Two control groups were also examined: those exposed below 0.0001 ppm and those exposed below 0.01 ppm. The results of this analysis for three latency periods are shown in the table below.

TABLE 1.—FREQUENCY OF LUNG AND RESPIRATORY SYSTEM MORTALITY

Lifetime average exposure (ppm)	Percent of total mortality from lung cancer			
	Years of latency assumed			
	0	5	10	20
0-0.0001	5.5	4.6	4.6	5.5
0-0.01	6.4	6.4	6.4	6.3
>0.01 - <2	8.1	8.3	8.5	10.6
>0.05 - <2	8.8	9.2	9.7	11.0
>0.1 - <2	10.1	10.1	10.4	10.4

This analysis showed that about 5 percent of the "unexposed" population died of lung cancer, a little below the 6 to 7 percent expected for white males. Since the cohort is still young (many have not yet died) and lower mortality in workers than in the general population is expected, these results are reasonable. However, any exposure to formaldehyde was associated with an increased percentage of deaths from lung cancer. For all exposures above 0.01 ppm, there was an increased probability that death was from lung cancer.

The data show that the probability of dying from lung cancer is about 60 percent greater if average lifetime exposure exceeded 0.1 ppm formaldehyde. As exposure increased, the latency period seems to become less relevant to the increase in lung cancer risk in this analysis.

Robert Park of the UAW reanalyzed part of the Blair *et al.* data [Ex. 146-D]. Analysis was limited to white men who died between study plant entry date and January 1, 1980. Analysis was further limited to hourly workers and those with unknown hourly/salaried status (about 6%). Plants 2 and 10, studied previously by Marsh [Ex. 42-79] and by Wong of Tabershaw Associates, Inc. [Exs. 42-118; 42-129], were excluded. There were 2,598 deaths with 196 from lung cancer.

For each worker, Park developed a work history including estimated TWA exposures for each job held for 2 weeks or more, start and termination dates, proportion of jobs held where exposures were uncertain, and whether there was particulate exposure or any job with exposure over 2 ppm. Formaldehyde exposure was calculated using a latency weighting function which assigned relatively less weight to cumulative

exposures that occurred nearer to death. The weighted TWAs were then summed to estimate each worker's exposure.

Park used a logistic regression model to calculate the odds that deaths due to any particular cause were correlated with formaldehyde exposure or with other risk factors or confounders. The simplest model that provided the best fit to the data was a cumulative exposure predictor using a quadratic function. The expected odds were calculated from age- and year-specific proportional mortality rates.

Park found increasing odds of death due to lung cancer with cumulative exposures up to 80 ppm-months. Eighty ppm-months covered 92.7 percent of the exposures and 165 of the lung cancer deaths. Above 80 ppm-months, the odds leveled off and then declined.

There was a statistically significant negative trend with cumulative exposure and the odds of dying from non-malignant respiratory disease. Several other smoking related outcomes (arteriosclerotic heart disease and bladder cancer) also had reduced odds ratios in the highest cumulative exposure stratum. These latter findings suggested to park that cigarette smoking might be less in the high formaldehyde exposure group. Lower cigarette smoking in the high exposure group would selectively lower the lung cancer rate and flatten the lung cancer cumulative dose response curve.

Park examined data from plant 2 where high exposures occurred. Of 86 deaths, only one was from nonmalignant respiratory disease, with 5 to 6 expected. According to Park this observation added some biological support to Dr. Schneiderman's testimony that workers exposed to formaldehyde for longer periods of time may smoke less because of the irritating properties of formaldehyde on the respiratory system.

OSHA's Evaluation of Lung Cancer in the NCI Study: In the evaluation of lung cancer, a long period of observation may be necessary in order to allow enough time for cancers to become clinically recognizable. The Blair *et al.* study demonstrated a significant increase in lung cancer among all wage workers exposed to formaldehyde who had 20 or more years of latency as shown in Table 7 of the report (see Ex. 156-A4).

The data in the Blair report Supplemental Table 7 (see Ex. 99) also show a significant increase in lung cancer for all white men exposed to formaldehyde at levels above 0.5 ppm ($O=66$, $E=51.5$, $SMR=128$, $P<0.05$). These data are consistent with those from Acheson *et al.* [Ex. 42-1], which is described below.

Sterling and Weinkam [Ex. 200-1] analyzed the NCI data using a slightly different categorization scheme and reported a significantly elevated relative risk of lung cancer for workers exposed to formaldehyde at levels of 0.5 ppm or greater as compared to those exposed at less than 0.5 ppm. Using another surrogate of exposure, hourly versus salaried workers, Sterling and Weinkam also demonstrated a significantly increased relative risk of death from lung cancer. OSHA's analysis of the NCI data as presented by Sielken also suggests that there may be a trend of an increased risk of lung cancer with an increase in the average level of formaldehyde exposure.

Based on their analysis of lung cancer mortality as a function of cumulative dose, Blair *et al.* concluded that there was "little evidence that mortality from cancer is associated with formaldehyde exposure at levels experienced by workers in this study" [Ex. 156-A4, p. 1071]. There are several reasons, however, that may account for why Blair and his colleagues failed to find a dose-response relationship. First, exposure misclassifications will bias the results against finding a statistically significant dose-response relationship regardless of whether high exposures are classified too low or low exposures are classified too high.

Second, there is some indication that persons who were exposed at the highest cumulative doses of formaldehyde may have been less likely to smoke cigarettes [Ex. 96]. Analysis of the NCI data (Supplemental Table 4) by Park suggests a trend consistent with a lower frequency of cigarette smoking in the upper end of the formaldehyde cumulative dose response curve; there was a significant deficit in mortality from non malignant respiratory disease. Supplemental Table 4 also showed reduced mortality in the highest formaldehyde cumulative exposure group from smoking related deaths such as bladder cancer, arteriosclerotic heart disease and emphysema. Thus, the lack of a dose response between cumulative formaldehyde exposure and lung cancer may be a reflection of a lower frequency of cigarette smoking among those with higher cumulative dose of formaldehyde. This suggestion is further supported by the data in Blair *et al.*'s Supplemental Table 4, which shows a decrement in risk of lung cancer as the duration of employment increases. Thus, the data suggest selection bias against finding a dose-response relationship by duration of exposure and also by cumulative dose. Because of these observations, the Agency is of the opinion that cumulative dose is not the preferred measure of

dose to evaluate lung cancer in the NCI study.

Based on the above discussion, OSHA is of the opinion that formaldehyde played a role in the excess risk of lung cancer observed in the workers studied by Blair *et al.* [Ex. 156-A4].

The British Study of Lung Cancer: Acheson *et al.* [Exs. 42-1; 66-4; 73-2; 73-3] conducted a cohort mortality study of 7,680 men first employed before January 1, 1965 in six British chemical or plastics factories where formaldehyde had been manufactured or used. The cohort was assembled using company personnel files. Workers first employed after January 1, 1965, workers for whom essential information was missing (3.9%), and women were excluded from the study. The expected numbers of cause-specific deaths were calculated by person-years using national (England and Wales) rates adjusted for age, sex, and calendar period. SMRs were also calculated using local rates for 1968-78 for lung cancer and 1969-73 for deaths from chronic bronchitis. By the end of the follow-up period, December 31, 1981, 21 percent of the cohort had died. Only 2 percent of the study population was lost to follow-up.

Exposure measurements before 1970 were not available, so the investigators subjectively categorized each worker's exposure from job descriptions into one of four categories: high (>2.0 ppm), moderate (0.6-2.0 ppm), low (0.1-0.5 ppm), and background (<0.1 ppm). The year of first formaldehyde manufacture or use varied by factory; Plant 1-1955, Plant 2-1920, Plant 3-1950, Plant 4-1937, Plant 5-1937, Plant 6-1948. At all six factories, some formaldehyde was likely to have been inhaled as particles, either from paraformaldehyde or formaldehyde-based products. For all cohorts combined, 35 percent had been exposed to high (>2.0 ppm) concentrations and 25 percent to background levels, but plant 4 (British Industrial Plastic or BIP) contributed almost all (91%) the workers who were heavily exposed.

Compared with national rates, a significant excess of lung cancer ($SMR=124$, 95% $CI=104-148$) existed among workers employed at the BIP factory where workers experienced the relatively highest formaldehyde exposure level. Significant excesses of lung cancer were not observed at the other five plants, nor were they observed at BIP when local cancer rates were used to calculate expected mortality. There was also a borderline significant linear trend in increased mortality from lung cancer associated with formaldehyde exposure level. No

relation was found between mortality from lung cancer and length of service for BIP workers categorized as exposed to high levels of formaldehyde.

Mortality from lung cancer was evaluated to determine if it was related to time elapsed since first exposure to high levels of formaldehyde at BIP. Men who entered the BIP factory between 1936 and 1946 (when formaldehyde exposure levels were the highest) had the highest mortality from lung cancer; this was statistically significant when national rates were used as the comparison groups and of borderline significance when local rates were used. In addition, a significant excess of mortality from chronic bronchitis among BIP workers was observed over the follow-up period 1937-1981 (79 deaths observed, 57 expected SMR=138, 95% CI=109-172). The authors discounted the significance of this finding because the SMR for chronic bronchitis was 188 for the years 1969-73 in the county where the BIP factory is located.

Acheson *et al.* [Exs. 66-4; 73-2; 73-3] further analyzed lung cancer mortality for BIP workers by examining cumulative exposure and duration of exposure to formaldehyde. There was no relationship observed between cumulative dose of formaldehyde and incidence of lung cancer among the workers. Acheson *et al.* discussed the appropriateness of using either national or local rates for calculating the SMRs for lung cancer. They were of the opinion that it would be preferable to use national rates if occupational factors were responsible for the elevated lung cancer rates in the area where the BIP plant was located, whereas it would be preferable to use the local rates if smoking habits or air pollution were responsible for the elevated rates. The authors concluded that the results of this additional analysis contradict, but did not rule out, the view that formaldehyde is a lung carcinogen in humans.

According to Dr. Schneiderman, the Acheson *et al.* report showed an excess of lung cancer, with a significantly positive dose-response relationship in one of six factories. Acheson did not believe his findings to be important in view of local lung cancer rates and the fact that the dose response for lung cancer and formaldehyde exposure level was seen in only one factory. Dr. Schneiderman disagreed, stating that the BIP factory was the oldest of the group Acheson examined, it had the largest work force, and higher exposure levels than the other factories examined. Dr. Schneiderman noted that local rates cannot explain an apparent dose-response relationship and might instead

obscure significant findings [Tr. May 7, 1986, pp. 46-47].

In response to a question from the OSHA panel regarding the use of local rates instead of national rates, Dr. Schneiderman replied that he is uneasy, in general, about using local rates when looking at an industrial population unless he knows that it is the only industrial population in the community. Otherwise, if exposures occurring in some of the other industries also lead to increased cancer rates, rates in a specific industry are being compared to elevated rates in the community. Thus, Acheson *et al.*'s finding that the lung cancer rates for workers at the BIP plant were not excessive, in such circumstances, is simply a finding that employees in one industry are no worse off than the other people who work at other industries in the community [Tr. May 7, 1986, p. 147].

Dr. Sidney Shindell also expressed concern that the use of local comparison groups with higher than usual lung cancer rates may have obscured an independent effect of formaldehyde [Ex. 44-24].

OSHA's Evaluation of the British Study: The study by Acheson *et al.* provides one of the relatively more detailed studies of industrial workers exposed to formaldehyde. The major finding was the observation of a significant excess of mortality from lung cancer among workers exposed to formaldehyde at BIP—the plant where the greatest percentage (73%) of workers were exposed to formaldehyde at levels estimated to be over 2 ppm.

The observation of a significantly increased risk of death from chronic bronchitis compared with national rates (79 deaths, 57 expected, SMR=138) among the same workers that experienced lung cancer is noteworthy in view of reports of asthma and pneumonitis associated with occupational exposure to high levels of formaldehyde (see 50 FR 50441-50442, which is hereby incorporated by reference). The local area SMR for bronchitis during 1969-73 was 188.

Acheson *et al.* demonstrated a borderline significant dose-response relationship among BIP workers between average exposure to formaldehyde and risk of dying from lung cancer. The authors tended to discount the relationship because of a lack of a relationship between cumulative dose of formaldehyde and lung cancer mortality. They stated that the trend, which followed the exposure level (measured in ppm), disappeared when duration of employment was considered because many "high"

exposure men worked for only short periods of time at those levels. Presumably they did not accumulate a large total dose. However, the dependence on concentration and not on cumulative exposure is consistent with studies of cellular turnover rates in the rat nasal mucosa [Ex. 73-79]. Furthermore, Acheson *et al.* demonstrated that workers who entered the BIP factory prior to 1945, when exposure levels were highest, demonstrated a significant excess of death from lung cancer. The results, are consistent with those found in the Blair *et al.* data.

Acheson *et al.* also discounted their observations of a significant excess of lung cancer among BIP workers exposed to formaldehyde because analyses based upon a crude adjustment with local lung cancer rates for the period 1968-78 raised the expected number of lung cancer deaths from 103 to 124 as compared to 128 deaths observed from lung cancer over the period 1941-1981.

The reanalysis based on local rates may not be appropriate, for the following reasons. First, because of the risk of lung cancer from smoking there has been a secular increase in lung cancer. Using rates for 1968-78 to estimate expected deaths in the cohort followed over the period 1941-81, therefore, would overestimate the number of expected deaths and bias the results toward an underestimation of risk. Second, the application of a crude SMR for the 1968-78 period to the expected number of lung cancer deaths does not consider age distribution differences between the cohort and the local population. This results in a bias toward underestimation of risk if, as is usually the case, the occupational cohort has an age distribution younger than the general population. Third, in the absence of information related to other risk factors in the local area, e.g. air pollution, smoking habits, and toxic chemicals used in other local industries, it is not possible to determine if the use of local rates is appropriate.

Other Studies of Lung Cancer: Coggon *et al.* [Ex. 73-13] conducted a case-control study of lung and bladder cancers using a job exposure matrix. Lung cancer cases and their matched controls were men under 40 years of age who died in England or Wales between 1975 and 1979. The underlying cause of death for lung cancer cases was cancer of the trachea, bronchus, or lung. Patients with tumors of nonepithelial origin were excluded. For each lung cancer case, two controls who died from other causes were selected by matching for sex, year of death, residence, and

date of birth. A similar method was used for bladder cancer cases and controls; these were men under 50 who died between 1975 to 1979.

Exposures to nine substances, including formaldehyde, were estimated based on job titles recorded on the death certificates. There were 2,263 occupations, and an industrial hygienist placed each person into any relevant unit according to his likely exposure to each of the nine substances. Within the matrix, exposures to each substance were categorized as high, low, or none. Relative risks for each occupation were calculated by examining the matrix units. Estimated risks for occupations with exposure were also examined in comparison to those with no exposure for a possible dose-response effect.

Of the 223 occupational units listed, cooks, military members, and construction workers showed a significant excess of lung cancer. Asbestos-related occupations showed a significant association with lung cancer as well as a dose-response relationship. No association was found between lung cancer and exposure to arsenic or chromates. Formaldehyde was associated with a significant excess of lung cancer (296 cases, 472 controls, $RR=1.5$, 95% $CI=1.2-1.8$, $p<0.01$), but there was no dose-response relationship. The investigators stated that the association between lung cancer and occupations involving formaldehyde exposure was "impressive". The existence of a direct causal relationship, however, is uncertain given the absence of an increased risk in jobs with high exposure.

Since the study failed to find significantly elevated risks from exposures to known carcinogens, the study appears to have a low power to detect excess risk, and that the results for formaldehyde might be viewed as potentially more meaningful than Coggon's statement implies.

Partanen and coworkers [Exs. 138.Z, 200-6B] examined 3,808 men who entered the formaldehyde-exposed workforce from 1944 to 1966. Fifty-seven had died of cancers judged relevant by the authors, *i.e.*, respiratory system and related sites. Average exposure was estimated to be 1 ppm with a mean duration of exposure of 10 years. Odds ratios (OR) were calculated for average formaldehyde exposure ($OR=1.44$), peak exposure ($OR=1.26$), and exposure to formaldehyde-containing wood dust ($OR=1.22$). The excess risk was not statistically significant even when allowance was made for a 10 year latency period; age; smoking history; and exposure to wood dust,

chlorophenols, pesticides, or terpenes. Wood dust exposure has been reported to be a confounding variable for formaldehyde exposure and nasal cancer, one of the types of cancer considered relevant, and Partanen's study, overall, involved few cases of cancer. In such circumstances, slightly elevated risk would be expected. The results are not inconsistent with studies which associate formaldehyde exposure with nasal cancer and with Coggon *et al.*'s lung cancer study [Tr. May 7, 1986, pp. 81-83].

In the NIOSH study of garment workers [Ex. 98-A] (see section below on oral cancer), a nonsignificant excess of cancer of the trachea, bronchus, and lung was seen in men. In white females, 22 cases were observed ($SMR=97$); in white men, 14 cases were observed ($SMR=133$); in nonwhite women there were two cases; and in nonwhite males, there was 1 case. Mortality was highest among workers with short durations of exposure and latency, when exposure was lowest, leading the authors to conclude that "this pattern is inconsistent with the hypothesis that the excess in respiratory cancer mortality is related to formaldehyde" [Ex. 98-A, p. 13]. OSHA notes that the results of this study are not consistent with the evidence regarding lung cancer and latency in other studies. Definitive conclusions regarding lung cancer in the NIOSH cohort are not possible because of the small percentage who have died.

Bertazzi *et al.* [Ex. 73-83] examined the mortality of 1,332 male workers employed at least 6 months between 1959 and 1980 in a plant that produced formaldehyde-based resins. There were 20,336 person-years accumulated during the observation period, and 98.6 percent of the cohort was traced. Lung cancer mortality (18 cases) was significantly increased compared to expected numbers based on national rates (7.6 cases) or local rates (9.7 cases). The authors did not find a trend according to duration of exposure or latency. When other plant workers were used as controls, there was no apparent excess of lung cancer. Given the limited information OSHA has on this study, which is reported as an abstract, it is difficult to determine the cause of the excess of lung cancer in this group. The results, however, are similar to those found in the Blair *et al.* study.

Nasopharyngeal cancer—the NCI Study: Among white men in the Blair *et al.* study [Ex. 156-A4], seven died of nasopharyngeal cancer [Ex. 200-4]. Five were exposed to both formaldehyde and to formaldehyde-bearing dust. Four of the seven were employed by the same company, a manufacturer of molding

compounds. For persons exposed to particulates, the risk of death from cancer of the nasopharynx increased with cumulative exposure to formaldehyde from an SMR of 192 for <0.5 ppm-years, to 403 for 0.5 to <5.5 ppm-years, and 746 for >5.5 ppm-years. Although the trend was not statistically significant, the authors felt that it showed a striking dose response gradient between nasopharyngeal cancer and cumulative formaldehyde exposure among workers also exposed to formaldehyde-containing particulates.

OSHA believes that formaldehyde concentration may be at least as important as cumulative exposure in the development of nasopharyngeal cancer (NPC). Indeed, information provided by the authors indicated that five workers who died from NPC had held jobs where formaldehyde exposure had excursions to levels exceeding 4 ppm.

The FI criticized Blair *et al.*'s analysis of NPC on the following points: 3 of the 7 cases occurred in short-term workers; the cases were clustered in a single plant of the 10 studied; there were no cases in workers with the highest exposure; and cursory treatment of particulates [Ex. 201-8, pp. 1-3]. OSHA evaluated each of these criticisms and found that none presents a convincing case for dismissal of the results.

There were too few deaths expected from NPC at each plant included in the cohort to provide sufficient statistical power to evaluate dose response at each facility. For example, at the American Cyanamid plant (plant 1) there were 4 observed NPCs versus only 0.43 expected ($P<0.01$). Some of the other plants in Blair *et al.*'s cohort also manufactured formaldehyde resins and molding compounds (see Ex. 156-A4), but these plants presented even greater limitations in statistical power to detect NPC. Plant 1, with the excess NPC deaths was one of the older and larger plants in the study, and it had the largest percentage of exposures ranked in the highest two of five categories of any plants making resins and molding compounds (see Ex. 156-A4). The exact locations of the high exposure operations, and the comparability of those operations cannot be ascertained from the data available to OSHA. However, Blair *et al.* noted that all the workers who died from cancer were exposed to formaldehyde at peak levels exceeding 4 ppm. Since plant 1 was relatively large and had higher exposures, an excessive risk of NPC in that plant suggests that formaldehyde could be the etiologic agent responsible for the excess risk.

The absence of NPC deaths among workers first entering employment before 1945 at plant 1 does not appear significant since only 14 percent of the American Cyanamid workers included in the cohort entered formaldehyde-exposed work by that time, but 54 percent entered in the next interval examined by Blair *et al.* (see Ex. 156-A4).

The treatment of particulates by Blair *et al.* is cursory, because the investigators did not measure exposure to particulate dusts. Since dusts from molding compounds should contain free formaldehyde (see Ex. 200-4), the employees who were exposed to molding compound dusts might have had a higher exposure to formaldehyde than calculated on the basis of the available exposure data, thus suggesting a higher formaldehyde exposure than was able to be measured. (See Stewart *et al.* on the industrial hygiene assessment.)

American Cyanamid criticized the Blair *et al.* conclusions regarding NPC on the grounds that the excess was found only in their plant, the researchers treated particulate exposures inappropriately, and the study did not find excessive NPC among long-term workers [Ex. 201-17]. Cyanamid also noted that all four cases in their plant were among persons first employed between 1949 and 1955. The commenter maintained that the absence of NPC among 931 workers first employed before 1946, when exposures were the highest, was significant.

While most of Cyanamid's criticisms were identical to those of the FI, and have already been addressed, Cyanamid also suggested that Blair *et al.* should have included formaldehyde exposure of the workers only when they were also being exposed to particulate dusts. However, if particulates containing formaldehyde influenced the dose response for formaldehyde and NPC, a lack of consideration of such particulates in the dose response analysis would in general bias the results toward finding no association between formaldehyde dose and NPC.

In criticizing the short-term nature of the exposure for two of the workers who developed NPC, Cyanamid stated that, "protocols for occupational studies routinely omit employees who work less than one year because of aberrant mortality patterns among short-term workers" [Ex. 201-17, p. 3]. OSHA does not accept this argument as meaningful because there are many studies of industrial workers that demonstrate a significantly elevated cancer risk among short-term employees. Short-term workers often have the dirtiest jobs and

hence experience the highest exposures to toxic substances. Most importantly for NPC and formaldehyde specifically, a dose response was observed.

Collins, Caprossi, and Utidjian of American Cyanamid [Ex. 201-17, Att. B] updated Blair *et al.*'s results for Plant 1, where four of the seven cases had occurred, to include data from 1941 through 1984 and four additional deaths identified through improved company records. None of the four additional deaths was from NPC, and the SMR calculated for NPC decreased from 920 to 715, which was still statistically significant.

Collins *et al.* [Ex. 201-17, Att. B] also compared NPC rates with cumulative exposure to formaldehyde and particulates (*i.e.*, they excluded all exposures to formaldehyde not in the presence of particulate dust). SMRs were 1,026 based on the single plant and 388 for the total white male population in the Blair *et al.* study. Both findings were statistically significant although a dose-response trend was not found.

While the authors stated that "the conclusion from our reanalysis is that there is no apparent relation between formaldehyde and particulates and nasopharyngeal cancer" [Ex. 201-17, Att. B, p. 14], OSHA has determined that formaldehyde has a role, independent from that of particulates, in the etiology of NPC. Therefore, the Agency believes that the analysis by Blair *et al.* which uses all formaldehyde exposures provides a more valid measure of risk than the analysis by Collins *et al.*

The Washington State Studies: Vaughan *et al.* [Exs. 200-2; 200-3] conducted a population-based case control study of cancer of the oro- and hypopharynx, nasopharynx, sinus, and nasal cavity to determine if occupational exposure to formaldehyde or residence in mobile homes was more prevalent among persons experiencing these cancers. The investigation was conducted in a 13 county area in western Washington. The estimated population in the area was 2.7 million. Cases were identified by the Cancer Surveillance System, a cancer registry operated as part of the Surveillance, Epidemiology, and End Results (SEER) program of NCI.

To be included as a case, the person had to be between 20 and 74 years of age at time of diagnosis. Eligible diagnostic dates were 1979 through 1983 for sinonasal cancer and 1980 through 1983 for pharyngeal cancer.

Controls were identified through random telephone digit dialing to persons listed as living in the area. Each number was called up to nine times, and persons similar in age and sex to the

cases were asked to serve as controls. If more than one person was eligible, one was randomly selected for interview.

In a structured 30-minute interview, cases and controls were questioned regarding medical, smoking, alcohol, residential, and occupational histories. If the case had died, the investigators attempted to interview the case's next-of-kin.

There were 415 cases potentially eligible for the study. Of these, 59 (14%) could not be located or were deceased with no known next-of-kin. Sixty-one (15%) were not interviewed because of physician or subject refusal. Of the 295 interviewed, 5 were found ineligible because of age and 5 had primary malignancies outside the scope of the study. The following cases were eligible and interviewed: oro- and hypopharyngeal cancer (OHPC)-205, nasopharyngeal cancer (NPC)-27, and sinonasal cancer (SNC)-53. Of the case interviews, 143 were with next-of-kin.

For controls, 96 percent of the households were successfully screened, and 83 percent of the eligible persons contacted completed the interview. Twenty-one were later determined to be ineligible due to age. This left 552 controls available for analysis.

Cases for whom next-of-kin interviews were necessary were more likely to be older, male, and have a diagnosis of OHPC. Non-respondent cases tended to be younger than interviewed cases but of a similar distribution with respect to sex, tumor site, and histology.

Occupational exposure was assessed by a job-exposure linkage system. The investigators first classified each job (by 3-digit occupational code and 3-digit industry code) into three categories: unlikely to involve formaldehyde exposure, possible exposure, or probable exposure. Jobs with probable exposure were then separated into two categories according to intensity of exposure. The estimates of likelihood and intensity were combined to yield four variables: high (probable exposure, high level), medium (probable exposure, low levels), low (possible exposure), and background.

Overall, subjects reported holding 4,244 separate jobs, of which 1,748 were unique. Of these, 148 were judged as potentially involving exposure to formaldehyde. Ten, including cementing and gluing operators in wood product manufacturing, dressmaking, and molding and casting in iron and steel foundries, were judged high. Twenty-nine, including carpentry, sewing machine operations, and furniture manufacture, were judged medium. One

hundred nine, including farm work, hairdressing, most ship and boat building, and labor in pulp, paper, and paperboard mills were judged low.

Four methods were used to summarize a subject's occupational exposure to formaldehyde. One relied on the maximum exposure category attained. The second was based on number of years in a job involving formaldehyde exposure. The third and fourth methods involved calculation of a weighted average, either with or without allowance for a 15-year latency period.

Estimates of relative risk were derived from calculation of the exposure odds ratios (OR). A multiple logistic regression model, which treats the log of the odds of disease as a linear combination of exposure and other risk factors, was used to assess potential confounding factors. For OHPC and SNC, adjustments were made for age, sex, smoking history, and recent drinking patterns. NPC was adjusted for smoking and race.

Even though the authors did not find statistically significant associations linking formaldehyde exposure to an increased cancer risk, there was some evidence of a dose gradient. For example, with a 15-year induction period, the odds ratio (OR) for OHPC increased from 0.9 for low exposure (score of 5-19) to 1.3 for high exposure (score of 20 or more). For NPC, corresponding figures were 1.7 and 2.1. When odds ratios were calculated based on data from interviewed cases, the OR for the highest exposure score increased to 1.7 for OHPC and 3.1 for NPC. This trend would be consistent with an implication of formaldehyde as the etiologic agent because live interviews would be expected to provide a more accurate and thorough exposure profile.

In addition to these suggestive findings, the investigators also reported significant associations between exposure to resins, glues, and adhesives, products known to release formaldehyde, and both SNC (RR=3.82, CI=1.1-12.9) and OHPC (RR=3.94, CI=1.5-10.1) [Ex. 202, p. 1].

The authors [Exs. 200-2; 200-3] cautioned that limitations in the study would tend to make the study less likely to detect a real risk. Most prominent, they stated, was uncertainty associated with formaldehyde exposure levels, which should have resulted in non-selective, or random misclassifications in both cases and controls. This biases results towards failure to find a positive association.

Next-of-kin interviews appeared to result in less recall of jobs, which would also conservatively bias the analysis

since some jobs with formaldehyde exposure might go undetected leading persons at risk to be assigned to the "nonexposed" category [Exs. 200-2; 200-3].

Finally, the small number of cases available, particularly for NPC and SNC, limited the power of the study to detect even moderate increases in risk. For OHPC, NPC, and SNC, the authors estimated that the minimum detectable risk estimates were 2.3, 5.1, and 3.6, respectively.

Several commenters criticized aspects of the Vaughan *et al.* study of occupational exposures. The United Paperworkers International Union (UPIU) [Ex. 201-5, p. 3] observed that classification of pulp and paperboard laborers as having low exposure and of dressmakers as having high exposure was inconsistent with the UPIU and NIOSH monitoring data for paper and textile workers, respectively. Misclassifications tend to obscure existing relationships between exposure and excess cancer risk, and they cannot enhance such a risk.

The FI commented that the cases and controls were not properly matched [Ex. 201-8, p. 34]. OSHA's review of this issue revealed that controls, on the average, were slightly younger and better educated than cases, which might slightly increase the apparent significance of findings if there was an age or socioeconomic bias.

OSHA notes the extremely low exposure potential for most of the workers in this study. Only 7 subjects, either cases or controls, ever held jobs judged as potentially involving high exposure. Of these, only 5 would have had exposures which ever exceeded 1 ppm according to OSHA's knowledge of these occupations. Of the jobs judged to potentially involve medium exposure, 36 of the 50 subjects were carpenters, probably exposed below 0.5 ppm. The remainder were cabinet makers or furniture assemblers and sewing machine operators, groups possibly exposed over 0.5 ppm. Thus, the overall low degree of risk seen in this study is consistent with the low exposures. Given the findings related to resin and glue work, OSHA believes that it would be inappropriate to conclude that the occupational study was negative.

Using the same subject group and the unconditional logistic model, the authors also examined the role of residence in development of cancers of the pharynx, sinus, and nasal cavity [Ex. 200-3]. Of the 27 NPC cases, 8 (30%) reported having lived in a mobile home since 1950 as compared to 82 (15%) of the controls. Of those who lived in a mobile home, 50 percent of the NPC cases reported a

duration of residence of 10 years or more versus 22 percent of the controls. When risk estimates were adjusted for the confounding effects of smoking and race, a strong and significant association remained between living in a mobile home for 10 or more years and risk of NPC (OR=5.5, 95% CI=1.6-19.4). For those who had lived in a mobile home 1 to 9 years, the odds ratio was 2.1 (95% CI=0.7-6.6). A trend test revealed that these differences were highly significant.

The authors explored the possibility that the risk of NPC associated with mobile home residence might be modified by occupational exposure to formaldehyde. Using their weighted scoring system for exposure with a 15-year latency correction, the authors considered anyone with an exposure score of 5 or more to be occupationally exposed to formaldehyde (NPC odds ratio for 5-19 was 1.7; for 20+, it was 2.1). For those subjects with neither occupational exposure to formaldehyde nor residence in a mobile home, the adjusted risk estimate was 1.7 (95% CI=0.5-5.7) compared with 2.8 (95% CI=1.0-7.9) for occupational exposure only, and 6.7 (95% CI=1.2-38.9) for both occupational and residential exposure.

In contrast to the occupational study where next-of-kin interview tended to miss jobs, causing possible underestimation of formaldehyde exposure, the researchers were confident that residence was accurately reported in next-of-kin interviews. Indeed, in most cases, the next-of-kin would have resided in the same home as the subject, so that the reporting of residence would be subject to less recall bias than job history when next-of-kin interviews are used.

While this study represents, at best, an indirect measure of formaldehyde, it should be more sensitive than the occupational assessment to detect the potential consequences of formaldehyde exposure. Residential exposure was probably greater than workplace exposure, especially from the standpoint of cumulative dose. Years ago exposure to formaldehyde in new mobile homes averaged as much as 0.5 ppm [Exs. 42.31; 42-57] and easily reached or exceeded 1 ppm [Exs. 42-34; 42-78; 70-27]. Although the airborne concentrations decreased over the years as the mobile home aged and the available free formaldehyde was released, home residents could be exposed up to 168 hours a week, while workers' exposure is generally limited to 40 hours a week. Persons residing in mobile homes could have been exposed to formaldehyde since birth, an important consideration since persons

as young as 20 were included in the study. A 20-year-old worker could not possibly have met minimum latency requirements for cancer induction; a 20-year-old mobile home-resident could have met these criteria.

The FI criticized the Vaughan residential study on the following points: selection of controls would understate mobile home residence; socioeconomic factors such as drinking, smoking, and respiratory disease were not taken into account for NPC; no correction for age or sex for NPC; residence in pre-1960 mobile homes would not implicate formaldehyde (2 of 4 cases with first exposure more than 10 years ago); and chance was a plausible explanation for the results [Ex. 201-8, p. 4].

Opinions that methodology would underestimate mobile home residence in controls were based on the investigator's use of telephones for interviews and the expectation that mobile home residents would be less likely to have telephones. Dr. Vaughan explained that to be included in the study, all subjects, both cases and controls, had to have telephones. Thus, any cancer case that lived in a mobile home without a telephone was not included in the study [Ex. 201-3d, p. 3]. Therefore, OSHA believes that the selection process for the comparison group was valid and that telephone interviews did not understate mobile home residence in the controls.

Vaughan *et al.*, in a detailed report to the EPA, have demonstrated that the study model took into account important socioeconomic factors, age, and gender. Vaughan *et al.* stated [Ex. 202, p. 36]:

Since there were only 27 cases of NPC, sex and age were omitted from the final models to preserve precision. Inclusion of these variables did not alter the risk estimates to any appreciable degree. Smoking was determined to be a weaker risk factor for NPC than for OHPC * * *. The risk associated with 40 pack-years of smoking is estimated to be 2.0. There was no detectable risk for alcohol intake.

Vaughan *et al.* were concerned about socioeconomic status because their data indicated that the mobile home dwellers had less education than controls. When education was used as the variable, however, they found that social class was not a strong predictor of NPC risk [Ex. 201-3d]. Thus, OSHA believes that Vaughan has addressed the concerns expressed regarding potential biases.

OSHA agrees that, as the FI suggested, some of the cases may have been caused by factors other than formaldehyde. NPC, while rare, exists with a background rate of approximately half that seen in the

mobile home residents. Thus, the study never implied that mobile home residence, which resulted in formaldehyde exposure, caused all identified cases of NPC. Where there is a background incidence of cancer, arguments designed to isolate certain cases (and not controls) that may have been due to factors other than formaldehyde are especially unpersuasive.

Vaughan commented on chance and confounding in a letter to EPA regarding Dr. Cole's critique of the study (see Ex. 200-6A). According to Vaughan:

The discussion on chance could be written about any epidemiologic study and really adds nothing * * *. I do not fully agree with his [Cole's] multiple testing comments. This was not a fishing expedition; mobile home history was *a priori* the most important residential variable available [Ex. 201-3d, p. 2].

Vaughan, OSHA, and other parties have agreed that a limitation of the study is that it used only indirect measures of formaldehyde exposure [Exs. 201-3d; 201-8]. The small number of cases of NPC included in the study make it relatively unlikely however that one would find an association between NPC and any potential etiologic factor.

Dr. Imbus [Ex. 201-8, Att. 6, p. 3] pointed out that while SNC, NPC, and OHPC are three distinct diseases, extreme care must be exercised to ensure that there is no misclassification, especially in late diagnosis when the primary site may be obscured.

According to Dr. Imbus, anatomically, the regions are very close and SNC can be confused with NPC which might in turn be confused with OHPC. In addition, the FI submitted a letter by Dr. Bernard Wagner, Editor of Human Pathology magazine, in which Dr. Wagner described the difficulties faced in attempting to distinguish NPC and OHPC [Ex. 154]. These concerns appear to be overstated. Indeed, Drs. Imbus and Wagner are raising a technical point, the difficulty of determining the "primary anatomical point of origin" [Ex. 154], and not of determining correctly where a particular tumor is at the time of observation. The Vaughan *et al.* study's reliance on information extracted from data collected for NCI's SEER program gives OSHA an additional measure of confidence in the collection and coding of the data.

OSHA's Conclusions Regarding Nasopharyngeal Cancer: OSHA carefully reviewed the Washington state studies, including the contractor report; the Blair *et al.* report on nasopharyngeal cancer; and comments to the record regarding these studies. OSHA has determined, based on these studies

(notwithstanding their limitations) that formaldehyde exposure is probably associated with the development of nasopharyngeal cancer in humans. The studies evaluating an association between formaldehyde exposure and NPC are biased toward not finding an association because of small sample size and methodology used to determine exposure; yet three studies indicate an increased risk. The Blair *et al.* study demonstrates a significantly increased risk of NPC among "formaldehyde exposed" workers ($O=6$, $E=2.0$). Likewise, an analysis by Blair *et al.* demonstrated a borderline significant trend of increased relative risk of NPC with increasing cumulative dose of formaldehyde with particulates. Because of the small number of expected deaths from NPC in the total cohort exposed to formaldehyde, it is unlikely that such a trend would be observed. Whether this observation is due to formaldehyde and particulates or formaldehyde alone is difficult to determine as Blair *et al.* pointed out that all of those with such combined exposure "held jobs with hourly excursions exceeding 4.0 ppm formaldehyde". Thus, an analysis simply by level of exposure to formaldehyde in relation to NPC (which was not carried out) would probably show an association between NPC and formaldehyde. Dr. De Vita, the Director of NCI testified at Congressional oversight hearings that formaldehyde caused the NPCs which were found in the NCI study [Ex. 158].

The findings by Blair *et al.* are in line with those by Vaughan *et al.* who demonstrated a significantly increased risk of NPC among individuals who resided in mobile homes. The relative risk was 3.0, $P<0.05$. The relative risk went from 2.1 for those who resided in mobile homes for 1-9 years, to 5.5 for those who resided for over 10 years. Vaughan *et al.* were of the opinion that an increase in risk of NPC with increasing length of residence reinforced their observations of a significant increase in the risk of NPC observed with all periods of residence combined. Vaughan *et al.* also reported a nonsignificant elevation in NPC in relation to occupations with potential for formaldehyde exposure. Overall, the highest relative risk (6.7) was seen for those with both residential and occupational exposure to formaldehyde. On the basis of these reports, OSHA believes the most likely cause of the elevated risks of NPC in these groups is exposure to formaldehyde.

Oral Cancer: Stayner *et al.* conducted a retrospective cohort mortality study of workers exposed to formaldehyde in the

garment industry [Ex. 98A]. Workers included in the cohort were exposed to formaldehyde for at least three months because of their employment at one of three facilities producing permanent-press garments. A total of 11,030 workers contributed 188,025 person-years to the study. Vital status was successfully ascertained for over 96 percent of the cohort. Death certificates were obtained for all but 22 of the 609 deaths observed. The study population was primarily white (75.6%) and female (81.8%). The median duration of exposure was 3.2 years and the median latency was 15.8 years. Almost half the workers (42%), accounting for 57 percent of the person-years, were first exposed to formaldehyde before 1962. The cohort was predominantly middle-aged with a median year of birth of 1938.

Extensive industrial hygiene monitoring was performed by NIOSH. Formaldehyde exposure concentrations were obtained for 40 percent of the current employees in five departments at all three facilities. The geometric mean of the exposures was nearly identical in the three plants, from 0.14 to 0.17 ppm. Continuous area monitoring revealed that formaldehyde levels were relatively constant over the workshift with no substantial peaks or intermittent exposure.

A modified lifetable analysis was used to compute expected deaths by cause from 5-year age, 5-year calendar time, race, and sex specific mortality rates for the U.S. population.

Mortality from all causes (SMR=74) was less than expected, which the authors noted was consistent with other studies of industrial cohorts. Mortality from all malignant neoplasms was also less than expected. However, specific malignant death categories were in excess. Mortality from cancer of the buccal cavity (SMR=343, CI=118-786) and connective tissue (SMR=364, CI=124-832) was significantly elevated. The excess in buccal cavity cancer was also significant in white females (SMR=485) and in employees of plant 2 (SMR=886). Cancer of the buccal cavity (SMR=705) was significantly elevated among workers with 20 or more years of latency, and mortality (SMR=440) was highest in workers employed in the earliest time period (1955 to 1962). No cases of nasal cancer were observed, which the authors noted could be the result of limited statistical power to detect this rare form of cancer, since even one nasal cancer in the cohort would have represented a great excess over the expected rate.

Two of the four buccal cavity cancers were in the parotid gland, one was a cancer of the oral mucosa, and the other

was in the soft palate. The person who developed cancer of the oral mucosa used snuff, indicating that smokeless tobacco might be related to this cancer. Two pharyngeal cancers were observed, as compared to 0.29 expected, $P < 0.05$. Both were squamous cell carcinomas of the tonsils.

Dr. Sidney Shindell reviewed the NIOSH garment worker study on behalf of the American Apparel Manufacturers Association (AAMA) [Ex. 187]. Dr. Shindell listed several criteria for determining if an epidemiology study provides evidence that a suspected factor is the cause of a disease. He contended that the NIOSH study failed to meet any of these criteria, which included: strength of association, consistency, dose-response relationship, chronological relationship, specificity, and biological plausibility. Shindell criticized the strength of the association because of the small numbers of cancers involved and the large number of subsets examined. He also claimed that the results are inconsistent with the other studies of formaldehyde and that formaldehyde must act at the point of contact making the buccal cavity cancers implausible.

NIOSH conducted an in-depth review of the records available on the buccal cavity cases identified [Ex. 98] and disagreed with Dr. Shindell. The specific buccal cavity cancers seen could have plausibly had contact with formaldehyde according to the investigators, thus making it unnecessary to invoke an argument that formaldehyde caused cancer at a site remote from the point of application.

The maximum latent period for formaldehyde exposure in the garment industry is limited by the date of introduction of the permanent-press process, which was in the late 1950s [Ex. 70-14]. The study population consisted primarily of middle-aged females, of whom only 5.5 percent had died. These circumstances limit the ability of the NIOSH study to detect adverse effects from exposure to formaldehyde. Consequently, OSHA has treated this study as providing some evidence of an association between formaldehyde exposure and oral cancer but not necessarily a causal relationship.

Stayner *et al.* [Ex. 98-A] also reviewed evidence from earlier studies that suggested a possible relationship between formaldehyde exposure and development of buccal-pharyngeal cancer. For example, Liebling *et al.* [Ex. 42-74] found two cases in a small group of workers. Embalmers in New York state had a two-fold excess of buccal-pharyngeal cancers, but funeral directors, who had lower potential for

exposure to formaldehyde, did not [Ex. 42-124]. Matanowski found two cases of hypopharyngeal cancer in a study of pathologists [Ex. 42-81]. As described in detail before, Blair *et al.* and Vaughan *et al.* also found excesses of nasopharyngeal cancer in industrial workers and mobile home residents. Other studies [Exs. 42-1; 42-58; 42-79; 42-129; 73-42] have not detected an excess of buccal-pharyngeal cancers. The discussion of these studies, which appeared in the proposal, is incorporated by reference.

Brain Cancer: According to Thomas and Waxweiler [Ex. 175-7] very little is known about the etiology of brain tumors but several associations with occupation, environment, and genetics have been made through epidemiologic research.

Studies of chemical plant workers exposed to formaldehyde show inconsistent, but generally negative results regarding brain cancer risk. A cohort mortality study [Ex. 42-129] of 2,026 workers at a large formaldehyde-producing plant suggested that workers hired before 1961 had an elevated brain cancer risk. Two of the 3 persons with brain cancer died after a latency period of 10 years. A PMR study of workers at another plant that produced formaldehyde and formaldehyde-bearing resins did not show an elevated frequency of brain cancer [Ex. 42-73]; however, only 136 decedents had been exposed to formaldehyde. The Acheson report on 7,680 British workers exposed to formaldehyde indicated a statistically significant deficit of deaths from brain cancer ($O=5$, $E=12.5$) [Ex. 42-1]. The Blair *et al.* study of 26,561 workers [Ex. 156-A4] reported an SMR of 81 for white male workers exposed to formaldehyde at concentrations in excess of 0.1 ppm versus 102 for those exposed below 0.1 ppm. Incidences in females and black men were too small for meaningful analysis.

A study of 47 glioma cases diagnosed in 1979 and 1980 in Milan indicated a two-fold excess risk of glioma among textile workers (Musiccos *et al.* in Ex. 175-7). However, the resulting odds ratio of 2.1 was not statistically significant. About 20 percent of the cases had worked in the textile industry where formaldehyde and other chemicals were used.

Members of the Royal College of Pathologists who were alive in 1973 were followed to determine vital status to 1981 [Ex. 42-58]. Although fewer than two brain cancer deaths were expected among the 2,300 men, 6 died from brain cancer; all 6 had worked in hematology. The authors could not determine the

cause, but they believed that social class was not a factor in the etiology of this tumor, in part because there was no excess of brain cancer in medical practitioners as a group and because the SMR for the highest social class was only 108. Anatomists, who are exposed to similar chemicals, had a significantly elevated brain cancer risk compared with the U.S. general population [Ex. 73-42]. When they were compared with another professional group (psychiatrists), the anatomists' risk remained significantly elevated. Risk appeared to increase by duration of employment, but it was also elevated for those employed less than 20 years.

PMR studies of deaths occurring among funeral directors and embalmers in New York and California indicated elevations in the frequency of brain cancer deaths [Exs. 42-124: 73-43]. Among white men in the New York study who were licensed only as embalmers, and thus likely to be most heavily exposed, there was a 2.5-fold excess of brain cancer. A cohort mortality study of Ontario embalmers [Ex. 70-34] did not show an excess brain cancer risk. OSHA notes, however, that the study group was small and that no data were generated based on latency or duration of exposure [Ex. 175-7]. Matanowski [Ex. 42-81] provided data on the mortality experience of male pathologists; brain cancer deaths occurred more frequently than expected. Embalming fluids consist of preservative, modifying agents, anticoagulants, surfactants, coloring agents, deodorants, and vehicle [Ex. 39-D]. Only the exposure to formaldehyde was thought to have health-related significance [Ex. 39-C].

Female cosmetologists in Connecticut had an elevated incidence of brain cancer (Teta *et al.* cited in Ex. 175-7). The excess was more prominent among those who began hairdressing school between 1925 and 1934 (observed=6, SMR=2.02). Cosmetologists are occupationally exposed of numerous chemicals including formaldehyde solutions, hair dyes, permanent wave solutions, and other cosmetic preparations.

Thomas and Waxweiler [Ex. 175-7] listed several limitations on the evaluation of brain cancer risk and occupation from presently available studies. Most of the information was from mortality studies that lacked statistical power to evaluate specific occupational risk factors adequately. The observed and expected numbers of cases in most of the industrial studies were very small. Exposure information was ascertained by interview or work

history and not through monitoring. In most instances, workers had multiple exposures, and risks due to any single substance were not distinguished.

OSHA's Conclusions Regarding Brain Cancer: OSHA is unable to reach a determination that brain cancer is caused by exposure to formaldehyde. Brain cancer has been found consistently in "professional workers", but not in industrial workers. Simply lumping both groups together, as Dr. Cole did to reach his conclusion that there is an overall null result, ignores differences in mode of exposure to formaldehyde.

The view that brain cancer is not related to formaldehyde exposure because excesses have not been found in industrial groups with formaldehyde exposure was addressed by Dr. Schneiderman in his testimony. Dr. Schneiderman [Tr. May 7, 1987, pp. 47-487] pointed out that the "professionals" appear to be older at the time of death than the industrial workers. Thus, a plausible argument consistent with the data available is that the latency period for brain tumor induction following formaldehyde exposure is very long relative to the latency period for lung cancer.

It has also been hypothesized that the excess of brain cancer, and possibly leukemia, in persons exposed to embalming fluid or other tissue preservatives containing formalin is an artifact explained by social class bias [Exs. 69-19-B1; 73-81C; Tr. Feb. 15, 1985, pp. 621-625]. In Dupont's data base, the relative risk of all cancer and brain cancer are 0.83 and 0.89 respectively, for wage role employees. The corresponding relative risks for salary role employees are 0.80 and 1.18 [Ex. 68-21].

Social class bias might account for some of the discrepancies seen. However, pathologists and morticians are not of the same social class even though both show an excess risk of brain cancer. Also, Harrington reported there is no excess of brain cancer, overall in medical practitioners in the U.K. [Ex. 42-58]. Stroup [Ex. 73-42] was unable to account for excess brain cancer in anatomists on the basis of social class, suggesting that social class bias does not explain all of the excess of brain cancer.

In weighing this evidence, OSHA finds merit in the view that subgroups within the working population may differ as to the likelihood of being diagnosed as having a brain tumor, but a social class bias has yet to explain all of the brain cancer excesses seen in professional workers.

Some scientists have viewed the brain as a biologically implausible site of action for formaldehyde [Exs. 77-43, p. 3; 100-A]. The basis for this point of view is threefold. First, formaldehyde is an extremely active chemical that causes cancer in animals at its immediate site of tissue contact. Second, metabolism studies show that free formaldehyde, once taken into the bloodstream, reacts virtually immediately with endogenous substances [Ex. 73-21]. Third, metabolites, once formed, that become part of the normal 1-carbon pool are nontoxic. Other parties have stated that, because formaldehyde is a naturally occurring substance in the mammalian organism, there should be a practical threshold or a tolerable level of exposure [Ex. 73-15].

OSHA recognizes that much of the formaldehyde distributed beyond the immediate contact site is converted to metabolites that are unlikely to be carcinogens. Virtually nothing, however, is known about potentially toxic minor metabolites. The Agency notes, however, that there has been a clear demonstration that formaldehyde-protein complexes can bind with DNA, a reaction that could lead to cancer. These interactions are discussed in more detail below.

In conclusion, OSHA finds that exposure to some substance present in the workplace probably contributed to the excess risk of brain cancer observed in professional workers who were occupationally exposed to formaldehyde. With the data at hand, however, the Agency has not been able to determine the role of formaldehyde or any other exposure in the excessive brain cancer risk among these persons.

Other Sites: There is some evidence of an increased risk of leukemia among these professional groups of workers. Levine [Ex. 70-34] found a nonsignificant excess, 4 cases observed with 2.5 expected, in Ontario undertakers. Walrath and Fraumeni observed 12 cases of leukemia in California embalmers with only 6.9 cases expected, for a statistically significant PMR of 175 [Ex. 73-43]. These same investigators found a nonsignificant elevation of leukemia in New York embalmers, with 12 observed and 8.5 expected for a PMR of 140 [Ex. 42-124]. Stroup [Ex. 73-42] examined anatomists and found an excess of leukemia ($O=10$, $E=6.7$) compared with U.S. white male rates. The excess was attributable to a significant excess of chronic myeloid leukemia. Comments, evaluations, and conclusions regarding the role of formaldehyde in producing

brain cancer excesses also apply to leukemia.

With regard to other types of cancer the Consensus Workshop stated:

In individual studies, attention has been drawn to small excesses of death from cancer of the prostate, skin (including melanoma), kidney, bladder, and of the digestive system * * * In none of these sites, with the possible exception of prostate cancer, do the figures approach statistical significance in

either professionals or industrial workers. There is at present scant evidence of an association between exposure and cancer of any of these sites [Ex. 70-56, p. 339].

This report was prepared in 1983 and no substantial new information regarding these other potential sites has been developed since that time.

Summary of the Epidemiologic Studies: Table 2, below, summarizes the

major epidemiologic studies available on formaldehyde, placing special emphasis on results for cancer of the brain and respiratory system. These studies have been discussed in depth in either the preamble to the proposed rule or in this preamble to the final standard on formaldehyde but studies with followup information are omitted.

TABLE 2.—EPIDEMIOLOGIC EVIDENCE REGARDING FORMALDEHYDE AND CANCER

Study	Size	Cancer site	Observed	Expected
Cohort Mortality Studies				
Matanowski [Ex. 42-81] Pathologists	1,336	Brain.....	5	1.7
Pathologists	1,439	Lung.....	6	8.1
		Brain.....	1	1.2
Levine [Ex. 70-34] Morticians.....	1,477	Buccal cavity and Pharynx.....	1	2.1
		Lung.....	19	20.2
		Brain.....	3	2.6
		Leukemia.....	4	2.5
Harrington, Oakes [Ex. 42-58] Pathologists	2,307	Lung.....	9	22.0
		Leukemia.....	1	1.1
		Brain.....	4	1.2
Stroup [Ex. 73-42] Anatomists	2,239	Lung.....	12	43.0
		Brain.....	10	3.7
Acheson [Ex. 42-1] ¹ Chemical workers	7,680	Nasal cavity.....	0	1.1
		Lung.....	205	196
		Brain.....	5	12.5
		Leukemia.....	9	11.4
"High Levels" (BIP)		Lung.....	106	75
Bertazzi [Ex. 73-83] Resin workers	4,462	Lung.....	18	7.6
Blair [Ex. 156-A4] ¹ Chemical and production workers.....	26,561	Buccal cavity and Pharynx.....	18	19
		Nasal Cavity.....	2	2.2
		Nasopharynx.....	6	2.0
		Lung.....	201	182
		Brain.....	17	21
		Leukemia.....	19	24
20-yr latency		Lung.....	151	114
		Nasopharynx.....	3	1
Stayner [Ex. 98A] ¹ Garment workers.....	11,030	Buccal cavity.....	4	1.2
		Tonsil.....	2	0.3
		Brain.....	5	7.0
Proportionate Mortality Studies				
Walrath [Ex. 42-124] NY embalmers.....	1,132	Buccal cavity and Pharynx.....	8	7.1
		Lung.....	72	66.8
		Brain.....	9	5.8
		Leukemia.....	12	8.5
Embalmers Only.....	546	Buccal cavity and pharynx.....	7	3.5
Walrath [Ex. 73-43] California embalmers.....	1,007	Lung.....	41	42.9
		Brain.....	9	4.7
		Leukemia.....	12	6.9
		Buccal cavity and Pharynx.....	8	6.1

¹ See text for complete description of these studies.

Study	Size	Site	Odds ratio
Case Control Studies			
Brinton [Ex. 73-7] Textile workers	160	Nasal cavity and sinuses	1.7
Olsen <i>et al.</i> [Ex. 73-36] Cancer registry ¹	466	Nasal cavity and sinuses	2.8
Hayes <i>et al.</i> [Ex. 173] cancer registry ¹	116	Nasal cavity	2.5
Partenen [Ex. 200-6B] Cancer registry	57	Respiratory	1.4
Vaughan [Ex. 200-3] ¹ Mobile Homes	27	Nasopharyngeal	
		1-9 yr	2.1
		10+ yr	5.5
Resin & Glue [Ex. 202]	205	Oro- Hypopharyngeal	3.9
	53	Sinonasal	3.8

¹ See text for complete description of these studies.

Conclusions Regarding the Evidence From Epidemiologic Studies: Dr. Schneiderman, testifying for OSHA commented that if formaldehyde is a late stage carcinogen with some (smaller) early stage components, conventional measures of exposure would not be appropriate [Ex. 98, p. 21]. Rather, sporadic high peak exposures might be better correlated with response. Similarly, allowing for a latent period would have only a small effect in showing increased risks [Ex. 89, p. 22].

In contrast, Dr. Philip Cole, an epidemiologist testifying for the FI, contended that formaldehyde is not a human carcinogen because there is no unequivocal evidence that persons exposed to formaldehyde have an overall risk of dying of cancer. Dr. Cole cited information in Dr. O'Berg's testimony showing that in "at least 10 epidemiologic studies, * * * some 1,938 cancer deaths were observed as compared to 2,061 expected cancer deaths." This argument was presented by several other industry commenters, as well [Exs. 80-84; 164, pp. 5-8].

OSHA believes that overall cancer mortality is not an appropriate evaluation to determine causal relationships. Dr. Schneiderman, OSHA's expert witness who reviewed the epidemiologic evidence, testified [Tr. 5/7/86, pp 144-145]:

I would be surprised to find many materials that lead to an overall increase in all or most sites of cancer. That's saying that the mechanism makes no difference, that the tissue makes no difference, that this material works on all tissues * * *, and that's a little hard to believe, biologically * * *. I think there are very few materials that show increases [in cancer] in more than one or two or three sites.

OSHA agrees with Dr. Schneiderman's position. In fact, if a substance causes several life-threatening diseases in addition to cancer, the overall rate of cancer could even be diminished because of deaths from competing diseases.

Dr. Cole stressed that "patterns of strong, consistent findings greatly enhance a causal, or positive inference and consistency is even more important

for null results." From his examination of cancer incidence at specific sites (brain, leukemia-lymphoma, upper airways and mouth). Cole concluded that data on formaldehyde show extremely weak associations with SMRs close to 100, so that statistical significance cannot be used to exclude chance effects [Ex. 118, pp. 2-3].

For cancer of the nose and cancer of the oropharynx, Dr. Cole contended that "the picture is one of no association" because "there is no SMR over 160 except for one based on trivial numbers" [Ex. 118, pp 3-4]. OSHA rejects this argument because none of the SMR studies had sufficient power to detect even moderately high incidences of nasal or nasopharyngeal cancer. The Agency believes that the failure to detect cancer reflects the unlikelihood that they would be found in a small study population, not the absence of a causal relationship.

There is ample evidence in the record to indicate that case-control studies have the greatest chance of detecting extra risk from rare forms of cancer, and not the cohort mortality studies referred to by Dr. Cole. Of three case control studies, Hayes *et al.* found a strong association between formaldehyde exposure and nasal cancer, and Vaughan *et al.* found significant excesses of nasopharyngeal cancer associated with mobile home residence. The third study, by Olsen *et al.*, also indicated an association with nasal cancer. Two of three large SMR studies show an association between formaldehyde and nasopharyngeal cancer (formaldehyde resin-bearing dusts present) and oro-pharyngeal cancer (garment workers). Thus, epidemiological studies of formaldehyde exposure and cancer of the upper airways, rather than indicating lack of a relationship, consistently point toward an effect due to formaldehyde exposure.

Although Dr. Cole did not specifically address the Blair *et al.* paper or lung cancer risk from formaldehyde exposure, he commented on the use of dose-response in evaluating epidemiologic data:

It may reasonably be expected that, even in a study that concludes with an overall null

result, some highly exposed groups will experience an excess of cancer, if a cause-effect relationship exists. For none of the putative links between formaldehyde and cancer has a dose-response been demonstrated. True, this has not always been looked for; and true, a dose-response relationship can be difficult to demonstrate. Nonetheless, with an overall pattern of null results, I do not see how a causal inference can be supported unless there is convincing evidence that the heavily exposed, at least, are experiencing an adverse effect [Ex. 118, pp. 5-6].

The failure to find a consistent dose-response relationship, was used by Blair *et al.* to conclude that their study provided little evidence that formaldehyde was a carcinogen [Ex. 156-A4]. Numerous witnesses and posthearing commenters disagreed with Blair *et al.* and expressed the opinion that the Blair *et al.* study [Ex. 156-A4] provided evidence that formaldehyde has caused lung cancer. These parties stated that Blair's conclusions overemphasized the importance of finding a dose-response relationship. OSHA agrees and has concluded that Blair's information provides evidence suggesting a risk of lung cancer associated with formaldehyde exposure.

OSHA's conclusions are also based on the Agency's examination of three independent analyses (Sielken's trend test, Blair's data on average exposures, and Sterling and Weinkam's regression analysis) which show that lung cancer was more prevalent in persons in Blair *et al.*'s cohort who had average exposures above about 0.25 to 0.5 ppm (depending on individual definitions of exposure) than in persons with lower exposure. Average exposure, and not cumulative exposure, was also correlated with excess lung cancer risk in some British industrial workers. No other studies collected information on exposure concentrations, so that the nature of a dose-response relationship cannot be evaluated further. In contrast to Dr. Cole's assertion, OSHA finds that the two studies which included exposure estimates also demonstrated excess lung cancer among the groups with relatively higher average formaldehyde exposures; these exposure

levels were greater than 2 ppm in the Acheson *et al.* study and were 1.2 ppm in the Blair data.

There are numerous reasons why a stronger relationship with cumulative dose was not found. First, there may be no such relationship [Ex. 98]. Formaldehyde appears to be a weak initiator and a strong late-stage carcinogen, so effects observed in worker populations may primarily represent an acceleration in completion of a multistage process that was initiated by other environmental carcinogens.

Second, the largest groups exposed to formaldehyde and examined for mortality experience were exposed to low concentrations of formaldehyde. Accordingly, the risks would be only slightly elevated and difficult to define with statistical confidence. Historically, occupational exposures have been low relative to animal test data because workers do not tolerate the severe irritation caused by exposure to high concentrations of formaldehyde.

Third, social class bias should be expected for lung cancer [Tr. May 12, 1986, p. 8] because "professionals" (excluding embalmers) smoke less than industrial workers. Precisely such a relation is seen, suggesting that the general population may be an especially poor comparison group for determining lung cancer risks in anatomists and pathologists. Thus, a finding of lung cancer risk in industrial workers does not contradict the "professional" worker studies.

Regarding the deficit in lung cancer in the professional groups given the increases in lung cancer seen in Acheson *et al.*, Blair *et al.*, and Coggan *et al.*, Dr. Schneiderman stated:

This is another area in which there are social class differences * * * the higher the social class, the less cigarette smoking. So it may very well be that professionals are very low cigarette smokers, and this would lead, then, to lower lung cancer rates [Tr. May 7, 1986, p. 146].

The frequency of cigarette smoking in blue collar workers exposed to formaldehyde in relation to the general population may also complicate the analysis of lung cancer risk. While blue collar workers in general have a slightly higher frequency of cigarette smoking than the general population, formaldehyde workers may have a lower frequency of cigarette smoking because of the irritating properties of formaldehyde to the respiratory system. Thus, it is difficult to determine the effect of social class bias in terms of cigarette smoking on the true excess risk of lung cancer from formaldehyde exposure.

When OSHA published its proposal, the Agency was still attempting to deal with the results of positive animal data in light of epidemiologic studies of formaldehyde workers. While studies of embalmers and anatomists indicated an excess of brain cancer, these studies were unconvincing. These studies showed no excess risk of lung cancer, and they were too insensitive to detect any risk from rare cancers, all at plausible sites of action for formaldehyde, such as nasal or nasopharyngeal cancer. Under its Cancer policy, OSHA neither requires nor expects site concordance between animal studies and human sites. In some cases there are good reasons for the absence of site concordance. In drafting the proposed rule, however, OSHA could not plausibly explain how studies found excess brain cancer without also finding excess respiratory cancer. Furthermore, embalmers, who have highly intermittent exposures to formaldehyde, comprise a particularly unsuitable group for risk assessment by the methods available to OSHA. Thus, the Agency proposed alternative regulations in which formaldehyde might be treated as an irritant and a carcinogen or simply as an irritant.

Since the proposal has been published, the evidence regarding human risk of exposure to formaldehyde has become substantial. Case control studies indicate an excess risk of developing nasal cancer which cannot be attributed to wood dust exposure. The type of tumor seen in humans is the same as that observed in the rodents. Oro- and nasopharyngeal cancers have been seen in more than one study. Finally, a study of the British formaldehyde industry suggesting a possible excess risk of lung cancer has been corroborated in the U.S. industry.

Genotoxicity

Introduction: According to the OSTP report on chemical carcinogens, short-term tests, such as assays for point mutations, chromosomal aberrations, DNA damage, and *in vitro* transformations are useful to screen for potential carcinogens, to reach a judgment on the carcinogenicity of a chemical, and to provide information on carcinogenic mechanisms [Ex. 73-90, p. 7].

In addition, as stated by OSTP, "short term tests are presently limited in their ability to predict the presence or absence of carcinogenicity and cannot supplant data from long-term animal studies or epidemiological investigations since the tests do not necessarily screen for all potential means of cancer induction and do not necessarily mimic

all reactions that would occur *in vivo*" [Ex. 73-90, p. 17].

The system in which the greatest number of chemicals have been evaluated is the *Salmonella* microsome test where strains of genetically altered bacteria provide increased sensitivity to potential mutagens. Other microbial systems, not used as extensively, include cultured mammalian somatic cells, such as mouse lymphoma, Chinese hamster ovary, and Chinese hamster lung cells. The various systems are used to measure the capability of a chemical to interact with DNA giving rise to a mutagenic event. Although it has been widely assumed that neoplasia arises from mutation, none of the specific loci conventionally used in bacterial or mammalian cell mutagenic systems appear related to the cellular changes that occur in induction of neoplasia [Ex. 73-90, pp. 38-39].

Other heritable phenotypic changes in mammalian cells may also cause neoplasia through interactions with genetic material. A number of carcinogens cause structural alterations of chromosomes in the bone marrow of exposed animals or in cultured cells derived from various tissues. An assay used in conjunction with tests for chromosomal aberrations is the induction of sister chromatid exchanges (SCEs), believed to occur when damaged DNA recombines. It is also possible to identify the production of chromosome fragments (micronuclei) in reticulocytes or erythrocytes [Ex. 73-90, pp. 39-40].

Tests of unscheduled DNA synthesis, measures of DNA strand breaks, and assays based on differential growth inhibition of DNA repair proficient and deficient strains of *E. Coli* or *B. Subtilis* do not measure mutation, but DNA damage or the repair of such damage resulting from the chemical exposure [Ex. 73-90, p. 40].

Chemicals may have initiating and promoting properties, and the two properties are not mutually exclusive. Several short term *in vivo* bioassays to detect promoters include the mouse skin papilloma system and the strain A mouse test. The OSTP report considered these systems as intermediate in biological relevance between *in vitro* systems and the long-term animal bioassay [Ex. 73-90, p. 41].

In Vitro Tests: The genotoxic effects of formaldehyde have been studied extensively. The first suggestion that formaldehyde could induce genetic alterations appeared in a study of the fruit fly, *Drosophila*; this discovery was followed by studies in fungi and bacteria [Ex. 42-11]. In recent studies,

formaldehyde possessed weak mutagenic activity in the Ames *Salmonella* test [Ex. 42-119] and induced single-strand breaks in normal human fibroblast DNA [Ex. 73-76]. DNA-protein crosslinks in mouse leukemia L1210 cells [Ex. 73-165]. SCEs in hamster ovary cells and cultured human lymphocytes [Ex. 42-94]. SCEs in the mouse lymphoma forward mutagen assay [Ex. 42-23], chromosomal aberrations in human fibroblast cultures [Ex. 73-31], and mutations in a variety of cultured mammalian cells [Exs. 42-23; 42-52; 73-92C].

Extensive work has been conducted on the mutagenic effects of formaldehyde in the fruit fly. Exposure of adults or larvae to formaldehyde gas did not produce mutation, but injection of formaldehyde solutions into adults or feeding to larvae produced mutagenic activity in the males [Ex. 42-11]. For injected adults, mature sperm was most sensitive to mutagenic effects; in larvae, only the early spermatocytes were sensitive [Ex. 42-11]. Formaldehyde-treated food fed to larvae caused numerous genetic alterations, including dominant and recessive lethals, visibles, small and large deficiencies, inversions, and translocations [Ex. 94 p. 5].

The mutagenic activity of formaldehyde in *Drosophila melanogaster* larvae was confirmed recently by the genetic mosaic and sex-linked recessive lethal tests [Ex. 73-80] and possible reasons for formaldehyde's effects on *Drosophila* were suggested [Ex. 73-163].

Formaldehyde has been examined in various *Salmonella typhimurium* test systems. Golke [Ex. 73-77] found no effect at concentrations of up to 2 moles/plate in tester strains TA 1535, 100, 1538, 98, and 1537 indicating that neither base pair nor frameshift mutations had occurred. Brusick also found negative results in standard Ames *Salmonella* tests [Ex. 42-23], but Temcharoen and Thilly reported a positive mutagenic response in tester strain TM 677 [Ex. 42-119]. Formaldehyde failed to demonstrate activity in plate assays with TA 100 or TM 677, but both strains were mutated when the procedure was altered to include a liquid preincubation step [Ex. 42-32].

Chemicals which offgas from particleboard were also examined in the *Salmonella* test. Both mutagenic and toxic effects occurred in the bacterial tester strains. The pattern of mutagenicity and toxicity found was similar to that of formaldehyde [Ex. 70-19, Attachment IV, p. 10].

In mammalian systems, formaldehyde induced mutations in the mouse lymphoma cell forward mutation assay

employing the TK locus [Ex. 42-23]. In the dominant lethal assay, male mice were injected intraperitoneally (ip) with formaldehyde at 50 mg/kg. and they were mated to females during the week after exposure; the females showed a significant increase in postimplantation deaths. A significant increase in preimplantation deaths also occurred in females that were mated with males exposed 1 or 3 weeks earlier [Ex. 42-47]. Analysis of the spermatocytes of exposed males at metaphase I, however, did not reveal an increased incidence of chromosomal lesions [Ex. 42-47]. A separate investigation in mice injected ip at doses of 16 to 40 mg/kg found no evidence of dominant lethal mutagenesis [Ex. 42-43].

In addition to strictly mutagenic effects, formaldehyde has caused a number of related genetic effects in various organisms. In cultured cells, formaldehyde induced SCEs in human lymphocytes and in Chinese hamster ovary cells [Exs. 42-23; 42-94], and initiated cell transformation in C3H/10T1/2 mouse embryo fibroblasts [Exs. 42-17; 42-102; 73-1]. The cell transformation tests indicated that formaldehyde may act at an early stage in the carcinogenesis process. In contrast, formaldehyde was a weak promoter in C3H/10T1/2 cells when given following administration of a known initiating substance [Exs. 20-8; 42-48; 73-6].

Formaldehyde inhibited repair of O⁶-methylguanine and potentiated the mutagenicity of alkylating agents in normal human cells [Ex. 73-19]. Formaldehyde also induced mutations in human cells, suggesting that genotoxicity may be caused by a dual mechanism of direct DNA damage and inhibition of repair of mutagenic and carcinogenic DNA lesions caused by other carcinogens [Ex. 73-19].

The ability of formaldehyde to react with amino groups in amino acids, proteins, and nucleic acids may be an important property in explaining its mutagenic activity [Ex. 73-107]. Formaldehyde can bind to free amino groups and cross-link proteins by formation of a methylene bridge [Ex. 42-11]. Although formaldehyde does not react with pure double-stranded DNA, it will bind to single-stranded regions. Since single-stranded regions of the DNA occur at the replication fork, this is a possible site of action of formaldehyde [Ex. 94, p. 7].

Inside the cell, formaldehyde can react to form DNA-protein crosslinks [Ex. 94, p. 7]. These crosslinks have been identified in bacteria [Ex. 73-137], yeast [Ex. 73-123], and mammalian cells [Ex. 73-165]. The crosslinks were repairable

in repair-proficient strains of bacteria and yeast and in cultured mouse embryo cells. DNA damage caused by formaldehyde was also repaired in *Escherichia coli* where formaldehyde was more toxic to repair deficient strains than to a wild-type, repair proficient strain (Tweats, 1981, cited in Ex. 94, pp. 7-8). In human HeLa cell cultures, formaldehyde induced unscheduled DNA synthesis, an indicator of DNA damage and repair (Martin, 1978, cited in Ex. 94, p. 8).

Exposure of human bronchial cells, skin fibroblasts, and repair-deficient skin fibroblasts to formaldehyde resulted in DNA-protein crosslinks and DNA single-strand breaks [Ex. 73-20]. Formaldehyde was moderately cytotoxic to normal bronchial epithelial cells and fibroblasts at concentrations that induced DNA damage. When other genotoxic substances were administered along with formaldehyde, formaldehyde enhanced their cytotoxicity, suggesting that formaldehyde has promoter effects.

Other investigative groups observed single-strand breaks in the DNA of formaldehyde-treated cells [Exs. 73-122; 73-123; 73-165]. These strand breaks could have been a direct effect of formaldehyde or the products of DNA repair acting on other formaldehyde-induced lesions, such as DNA-protein crosslinks [Ex. 73-122].

In Vivo Tests: Studies of *in vivo* genotoxic effects of formaldehyde include the mouse spot test, the micronucleus test, and induction of chromosome aberrations or SCE [Exs. 42-23; 42-47; 73-28; 73-77]. These tests generally produced negative results [Ex. 70-23]. A slight increase in SCE was observed in the bone marrow of mice exposed to formaldehyde at airborne concentrations in excess of 25 ppm [Exs. 25-16; 42-23]. However, formaldehyde did not increase either SCE frequency or the number of metaphases displaying chromosomal aberrations in Fischer-344 rats exposed for 6 hrs/day for 5 days at 0.5, 6, or 15 ppm [Ex. 73-28].

Mice receiving three daily ip doses of formaldehyde and methanol showed a dose related increase in chromosomal aberrations, especially centric fusions, in bone marrow [Ex. 69-23-D5]. Urine from mice given formaldehyde orally, however, showed no mutagenic activity, and there was no evidence of abnormal sperm.

The strain A mouse lung adenoma system developed by Shimkin and colleagues is an assay system generally viewed as having greater biological relevance than *in vitro* systems since the test provides for *in vivo* metabolism and chemical disposition [Ex. 73-90].

The Texas Indoor Air Quality (TIAQ) study group [Ex. 70-19] examined formaldehyde in the strain A mouse test. The mice were given repeated intraperitoneal (ip) or oral doses of formalin or paraformaldehyde. Sixteen weeks later the animals were killed and the number of adenomas appearing on the lung surfaces were counted. Neither paraformaldehyde nor formalin increased the number of lung adenomas in mice by either route of exposure.

The TIAQ group also examined the effects of formaldehyde inhalation on lung tumor incidence in strain A mice. Groups of 30 mice were exposed at 0.5, 3, or 15 ppm for 6 hrs/day, 5 days/wk for 18 weeks. At the end of the exposure period, the mice were killed and the number of adenomas on the lung surface were determined. Lung tumor response was elevated in all experimental groups, reaching statistical significance in the 15 ppm exposure group.

Formaldehyde, when inhaled, also showed an ability to antagonize the known carcinogenicity of urethane. The authors speculated that this effect might be related to formaldehyde's capacity to inhibit DNA repair resulting in death of the carcinogenically transformed cells [Ex. 70-19].

In humans, there is little evidence of genotoxic effects at the relatively low exposures examined. A preliminary report noted an increase in SCEs in eight medical students exposed to formaldehyde at 1 ppm intermittently for 10 weeks during an anatomy class [Ex. 42-110]. A second study of six pathology staff workers exposed to formaldehyde at 1.14 to 6.93 mg/m³ (0.9-5.5 ppm) for 4 to 11 years and five unexposed controls, however, failed to detect differences in either induction of chromosomal aberrations or frequency of SCEs [Ex. 70-52].

Ward *et al.* [Ex. 77-19A] conducted a battery of tests to monitor for genetic damage in a group of 11 hospital autopsy service workers and 11 matched controls. Workers received intermittent exposures to formaldehyde that ranged from 0.61 to 1.32 ppm calculated as an 8-hour TWA. Subjects were matched for sex, age, and use of alcohol, tobacco, and marijuana. Information was collected on health, medications, and exposure to other toxins. Tests included sperm count, abnormal sperm morphology, and 2 F-body frequency (a measure of chromosome nondisjunction). Evaluation of confounding variables suggested correlations between reduced sperm count and marijuana use and between increased abnormal morphology and medications. No difference in any test was attributed to formaldehyde,

although the authors noted that their study was too small to detect slight changes.

Fleig *et al.* [Ex. 73-88B] conducted a cytogenetic analysis of the peripheral blood lymphocytes of 1 workers exposed to formaldehyde for 23 to 35 years in its manufacture and processing into resins. The workers had exposure to formaldehyde not exceeding 5 ppm before 1971 or 1 ppm afterwards. If gaps were excluded, workers had a slight increase in aberrant cells compared with in-plant controls.

Suskov and Sazonova reported that the average frequency of cells with chromosomal aberrations in peripheral blood lymphocytes was 5 percent in 31 workers exposed to phenol formaldehyde resins versus 2.4 percent in 74 control subjects [Ex. 17]. On the average, the workers were 39.1 years old, and they had worked with resins for 4 months to 30 years.

OSHA's *Analysis of Genotoxicity of Formaldehyde*: To summarize the studies available, *in vitro* tests of genotoxicity provide corroborating evidence that formaldehyde should possess carcinogenic activity. *In vivo* tests are of a limited nature and are not conclusive.

There are several reasons why *in vivo* studies might yield results different than the *in vitro* test systems. For example, Farber *et al.* [Ex. 73-15] attributed the differences, in part, to the metabolism of formaldehyde. They stated:

It is clear that at low exposures (*e.g.*, 1 ppm or less) formaldehyde is rapidly assimilated into the metabolic pool or bound to tissue proteins and other macromolecules thus reducing the amount of formaldehyde potentially available to interact with genetic material. This conclusion is supported by the results of studies in rats exposed to airborne concentrations of up to 14.3 ppm formaldehyde which failed to produce any detectable covalent binding in bone marrow cells (Casanova-Schmitz *et al.*, 1984) * * *. However, the results of these studies would not preclude the possibility that formaldehyde could induce mutations in epithelial cells of the nasal mucosa directly, especially at high airborne exposure levels. Likewise, one cannot rule out the possibility that formaldehyde may act in a promotional role [Ex. 73-15, p. 7].

The FI contended that the *in vivo* results in human studies were more relevant to human exposure than the *in vitro* results, and that on this basis, formaldehyde is not genotoxic.

Dr. Frederica Perera, a researcher at Columbia University who works in this field, disagreed with the FI position, stating that: "in general, *in vitro* systems are relevant and predictive indicators of effects that can occur *in vivo*. *In vivo* test methods tend to be insensitive and

it is very difficult to find suitable populations for study" [Tr. May 15, 1986, pp. 115-118].

For a number of reasons, OSHA agrees with Dr. Perera's assessment and concludes that the short-term tests for genetic toxicity are concordant with a finding that formaldehyde is a carcinogenic substance. First, the OSTP Guidelines stress that short-term tests should be carefully selected to ensure that they have been adequately validated [Ex. 73-90, p. 7]. While research remains ongoing, systematic efforts have been made to evaluate the ability of *in vitro* assays to detect or predict chemical carcinogens [Ex. 73-90, pp. 43-44]. No such effort has been extended to *in vivo* test systems. In fact, the FI criticized the ability of one *in vivo* system, the strain A mouse assay, to predict carcinogenic activity [Tr. February 13-15, 1985, pp. 16, 78-79]. Second, all of the *in vivo* evidence is not negative, even though few human subjects have been tested, and the tests have been too insensitive to detect anything but extremely obvious changes. Third, "it is believed that the primary initial site for cancer induction is the DNA" [Ex. 73-90, p. 15]. Evidence that formaldehyde interacts with DNA is sufficient alone to suspect that this substance would also be a carcinogen.

DNA Binding Studies: Several *in vivo* studies have demonstrated that formaldehyde interacts with DNA and is capable of cancer initiation. Investigations have found that formaldehyde causes chromosomal aberrations in alveolar macrophages and that formaldehyde covalently binds with DNA and protein in the rat nasal mucosa. The TIAQ Study investigators [Ex. 70-19 Attachment IV, pp. 1-7] determined the genotoxicity of formaldehyde in Sprague-Dawley rats at sites beyond the nasal passages. Tissues selected for analysis were alveolar macrophages, chosen to detect damage in the respiratory tract, and bone marrow cells, chosen to detect systemic damage. In one approach, changes in DNA and RNA content of the tissues were measured by flow cytometry. The tissues were also examined microscopically to assess chromosome damage.

Flow cytometry analysis demonstrated small but significant alterations in the RNA content of the macrophages as a result of inhalation of formaldehyde at 0.5, 3, or 15 ppm for 6 hr/day, 5 days/wk, up to 24 weeks [Ex. 70-19 E]. Consistent with the results of another experiment performed by Casanova-Schmitz and Heck of the CIIT [Ex. 62], the investigators found no

changes in either the DNA or RNA content of bone marrow cells.

Formaldehyde produced no observable cytogenetic damage to the bone marrow cells but a significant increase in chromosomal aberrations in the alveolar macrophages of the 15 ppm group. Chromosome breaks and centric fusions also were increased in some rats, but not in a dose-related manner. According to the authors:

These findings suggest that inhaled formaldehyde is capable of producing genotoxic effects in the lower respiratory tract of rats. It would seem prudent to explore these genotoxic effects in greater detail to determine if the carcinogenic activity of formaldehyde to the lower respiratory tract should be reassessed [Ex. 70-19, Attachment IV, p. 4].

Casanova-Schmitz and Heck extracted homogenates of rat nasal mucosa with denaturing organic solvent. Formaldehyde caused a loss of nucleic acids from the aqueous phase. The missing DNA and RNA, found at the interface between the aqueous and organic phases, could only be recovered after enzymatic proteolysis, indicating that protein crosslinking probably had occurred [Ex. 42-24].

To further examine this phenomenon, the investigators exposed rats to 0, 2, 6, 15, or 30 ppm of airborne formaldehyde for 6 hr/day for 2 days [Ex. 70-25, pp. 23-25, Fig. 3]. (Exposure for 2 days was intended to stimulate cell turnover, and increase the amount of single-stranded DNA). When they repeated the extraction procedure described above, the authors found a linear relationship between the percentage of respiratory mucosal DNA in the interfacial layer and the airborne concentration of formaldehyde.

According to the investigators [Ex. 70-25, p. 24]:

This finding constitutes the first evidence that inhaled formaldehyde may induce the formation of DNA-protein cross links *in vivo*.

The investigators recognized that the inability to separate DNA from proteins did not constitute proof of the formation of crosslinks with formaldehyde [Ex. 73-81H]. Testing this possibility led to the use of the dual radioactive labeling experiment based on the considerations described below.

Formaldehyde dehydrogenase (FDH) is an important enzyme in the metabolism of formaldehyde. FDH catalyzes the nicotinamide adenine dinucleotide (NAD⁺)-dependent oxidation of the formaldehyde adduct, S-hydroxymethyl glutathione, to form S-formyl glutathione [Ex. 70-23]. Some isozymes of aldehyde dehydrogenase catalyze the NAD⁺-dependent oxidation

of formaldehyde to formate. These enzymes are present at relatively high concentrations in rat nasal mucosa.

Metabolic pathways, such as those described above, that lead to the oxidation of formaldehyde result in the removal of one hydrogen atom from the formaldehyde. Formation of adducts and crosslinks does not involve the loss of hydrogen. Thus, in a dual labeling experiment, the ³H/¹⁴C ratio of macromolecules containing adducts or crosslinks with formaldehyde will be higher than for macromolecules labeled by oxidative metabolism [Ex. 62, p. 27]. Casanova-Schmitz and Heck took advantage of these properties to demonstrate the formation of covalent adducts or crosslinks between DNA and formaldehyde protein complexes.

Rats were exposed for 6 hours to 0.3, 2, 6, 10, or 15 ppm of formaldehyde to maximize single-stranded DNA. On the second day the rats were exposed to identical concentrations of formaldehyde, labeled with carbon-14 and tritium. At 6 ppm, a significantly greater amount of ¹⁴C was incorporated into DNA in the aqueous layer than into interfacial DNA, indicating that metabolism of formaldehyde was greater than DNA adduct formation. The specific activity of ¹⁴C-labeled DNA recovered in the aqueous layer also differed from that in the interfacial layer at the 6 ppm dose. This indicated that the two DNA structures, present in the aqueous and interfacial layers, differed; otherwise they could not have been separated by solvent extraction into portions with differing specific activities.

The ³H/¹⁴C ratio was quantitatively related to the fraction of formaldehyde covalently bound to the macromolecule. For respiratory mucosal interfacial DNA, the ³H/¹⁴C ratios increased with increasing formaldehyde concentration. At concentrations above 2 ppm, the difference between ³H/¹⁴C ratios of interfacial and aqueous DNA was statistically significant. Increases in the ³H/¹⁴C ratio of aqueous DNA were not observed, so that the increase in the fraction of DNA labeled due to covalent binding (*i.e.* adduct/crosslink formation) occurred only in the interfacial layer.

The concentration-response profile for covalent binding of formaldehyde to DNA was linear above 6 ppm, but non-linear at lower concentrations. The authors concluded from this:

The explanation for low-dose nonlinearity in binding of formaldehyde to DNA is not entirely clear at this time. However, at least two mechanisms could explain such nonlinear behavior. First, physiological and biochemical defense mechanisms, such as mucociliary clearance, metabolism, and

repair, could be inactivated or may become less efficient with increasing formaldehyde concentrations, resulting in a disproportionate increase in the concentration of DNA-protein crosslinks. Second, the marked increase in cell turnover caused by formaldehyde exposure at 6 ppm relative to that at 2 ppm could increase the availability of sites in the DNA for reaction with formaldehyde [Ex. 73-81H, p. 240].

To explore their hypothesis that oxidation of formaldehyde by the respiratory mucosa is a detoxification step, the CIIT investigators administered phorone to rats one hour after the second of two 6-hour exposures to formaldehyde [Ex. 73-81H]. The phorone caused a 90 percent reduction in nonprotein sulfhydryls (NPSH) in the respiratory mucosa for 5 hours before beginning to rebound. By depleting NPSH, the investigators were depleting glutathione, which is an essential activator of formaldehyde dehydrogenase (FDH).

Under conditions of depleted glutathione, the yield of crosslinked DNA from the respiratory mucosa was about threefold higher than in rats exposed to formaldehyde alone. The authors believed this research demonstrated that metabolism of formaldehyde, *i.e.* through oxidation by FDH, is an important defense mechanism protecting against cancer [Ex. 73-81H].

OSHA believes that studies showing DNA adduct formation indicate that formaldehyde is capable of initiating the carcinogenic process since DNA adduct formation occurred after only two days of exposure at 2 ppm [Ex. 85-84, Appendix p. 18]. These studies also imply that the site of tumor development should occur in the respiratory tract. This information, like the cytotoxicity data described in a later section, indicate that 2 ppm should not be considered a "no-effect level".

As described in other sections of this document, formaldehyde appears to be capable of acting at more than one stage in the carcinogenic process. Several sources of information indicate that formaldehyde is a late stage carcinogen as well as an initiator. Therefore, DNA binding studies conducted on animals exposed to formaldehyde for two days provide qualitative evidence that formaldehyde should be a carcinogen, but such information should be applied with great caution to the quantitative assessment of risk. OSHA also notes that other uncertainties exist in the use of these data for quantitative risk assessment as described by the EPA Expert Panel [Ex. 85-89]. While the CIIT investigators worked closely with the

EPA Panel and provided additional valuable information regarding their study, they were unable to repudiate all of the issues raised by the Panel regarding the utility of the study to predict human risk.

Cancer in Animals

Synopsis of the Data: In 1983, the Consensus Workshop on Formaldehyde [Ex. 70-56, p. 343] concluded:

Formaldehyde gas is carcinogenic for rats and probably for mice, producing nasal tumors after inhalation. Limited experiments in Syrian hamsters have not demonstrated carcinogenicity. In rats, the carcinogenic response appears nonlinear, being disproportionately higher at the higher concentrations (14 ppm).

In the Proposed Rule, OSHA concluded, based on the studies reviewed by the Consensus Workshop and new information, primarily the Tobe *et al.* report [Ex. 73-146] that formaldehyde should be treated as a potential occupational carcinogen:

[F]ormaldehyde has been shown to be a carcinogen in two strains of male and female rats in long term bioassays. This finding is supported by suggestive evidence of carcinogenicity in hamsters and mice and by positive findings in short term tests [50 FR 50446].

Evidence for the carcinogenicity of formaldehyde in animals was discussed in detail in the proposed rule [50 FR 50433-50437]. Briefly, the studies of greatest interest are chronic inhalation bioassays conducted by Battelle Columbus Laboratories for the Chemical Industry Institute of Toxicology (CIIT) [Exs. 12; 42-116; 42-131], by New York University (NYU) [Exs. 42-3; 42-4], by Tobe *et al.* [Ex. 73-146], and by Dalbey [Ex. 42-33], as well as skin painting studies by Spangler and Ward [Ex. 70-44] and Krivanek *et al.* [Ex. 70-43]. Only those studies pertinent to defining risk are repeated in this preamble to the final standard.

Experimental evidence in animals consisted of benign and malignant nasal tumors in Fischer 344 rats [Ex. 12], nasal cancers in B6C3F1 mice [Ex. 12], benign and malignant nasal tumors in male Sprague-Dawley rats [Exs. 42-3; 42-4] and in male Fischer 344 rats [Ex. 73-146], possible cocarcinogenic effects with diethylnitrosamine (DEN) in hamsters [Ex. 42-33], no increased risk of skin tumors in female CD-1 mice given dermal applications of formalin [Ex. 70-43], and inconclusive data regarding promotion of skin tumors in Sencar mice given formaldehyde applied to their backs.

The CIIT Study: In this inhalation bioassay of formaldehyde, exposure groups consisted of 120 male and 120

female animals of each of two species, the Fischer 344 rat and the B6C3F1 mouse. The animals were exposed for 6 hr/day, 5 days a week at concentrations averaging 2.0, 5.6, and 14.3 ppm over the course of the experiment. During the 24-month exposure period, microscopic examinations were conducted on animals killed at 6, 12, 18, and 24 months. To examine lesion recovery, some animals were retained after termination of exposure. All of the mice were killed at three months post-exposure, but some of the rats were retained until 6 months post exposure (30 months on study).

In the rats, there was a significant increase in squamous cell carcinoma of the nasal cavity in both males (51 tumors) and females (52 tumors) exposed to formaldehyde at 14.3 ppm. One male and one female rat exposed at 5.6 ppm also had a squamous cell carcinoma of the nasal cavity.

Two male mice exposed at 14.3 ppm had squamous cell carcinomas of the nasal cavity, observed only at necropsy at 24 months. The number of nasal cancers in mice was insufficient to show statistical significance, but they appear to be formaldehyde related and biologically significant because of their histological type and the rarity of such tumors in unexposed mice.

Microscopic evaluation of histological sections revealed increased incidences of epithelial dysplasia and squamous cell metaplasia in male mice exposed at 5.6 and 14.3 ppm and in female mice exposed at 14.3 ppm. During exposure, at least some mice from each exposure group developed rhinitis (inflammation of the mucous membrane of the nose).

All groups of rats exposed to formaldehyde had increased incidences of non-neoplastic lesions of the nasal cavity including epithelial dysplasia, squamous cell metaplasia, and rhinitis. Rats exposed at 14.3 ppm were most severely affected, with all three changes present in animals rats sacrificed after 6 and 12 months of exposure [Ex. 42-116]. Females from the 14.3 ppm group also had increased incidences of squamous metaplasia of the trachea. At 24 months, rats exposed at 14.3 ppm also had increased incidences of squamous atypia, squamous epithelial hyperplasia, and hyperkeratosis [Ex. 42-131].

In describing the lesions found in the nasal cavity of exposed rats, the authors [Ex. 42-131] stated that:

Apparent progression from squamous metaplasia to squamous epithelial hyperplasia with increased keratin production and then to areas of squamous papillary hyperplasia with areas of cellular atypia was evident in the high dose group only. More advanced lesions diagnosed as

carcinoma "in situ" and, finally, invasive squamous cell carcinomas of the nasal turbinates were present in rats from the intermediate and high exposure groups, but were statistically different from controls in the high exposure group only.

Additional information on the squamous cell carcinomas was obtained for 98 of 103 animals [Ex. 73-81G]. Single neoplasms were present in 40 male and 40 female rats exposed at 14.3 ppm. Nine additional males and 9 females had multiple neoplasms (21 and 20 tumors, respectively). More than half the squamous cell cancers occurred on the lateral side of the nasoturbinate and adjacent lateral wall at the front of the nose, about 25 percent were located on the midventral nasal septum and the roof of the dorsal meatus. A small number (2.5%) were found on the maxilloturbinate. The other regions of the nose did not contain any squamous cell carcinomas except as the result of invasion.

Histopathologic evaluation revealed the presence of 18 benign polypoid adenomas with similar morphologic characteristics in rats' nasal cavities [Exs. 42-90; 73-50]. The distribution of tumors was as follows: 1 in control animals, 8 in the 2 ppm exposure group, 6 in the 5.6 ppm group, and 3 in the 14.3 ppm group. Two animals with polypoid adenomas in the 14.3 ppm group also had squamous cell carcinomas of the nasal passages. A third rat in the high dose group had a malignant neoplasm with morphologic features similar to those of polypoid adenomas. The polypoid adenomas were confined to poorly ciliated epithelium in the most anterior part of the nasal cavity and were restricted to the free margins of the naso- and maxilloturbinates and the lateral wall adjacent to these margins.

In the CIIT study, the malignant nasal tumors in the high dose rats clearly caused early deaths [Exs. 42-22; 44-17]. Dr. Kenneth Brown performed statistical tests on the rat data [Ex. 42-22], and he found a significantly increased incidence of early deaths at all exposure levels, suggesting that there was a mortality effect due to formaldehyde inhalation aside from deaths attributable to nasal cancer. In contrast to the results in rats, Brown found no significant compound-related early mortality in the CIIT mice.

The CIIT bioassay included histopathologic analysis in the 14.3 ppm animals at sites other than the nasal passages [Ex. 12]. Clinical chemistry studies were also performed on the animals at each sacrifice period. OSHA reviewed this information to determine if there was any evidence of to brain

cancer or leukemia in these animals. Of 115 rats examined following exposure to formaldehyde at 14.3 ppm, 28 (24%) showed evidence of bone marrow hyperplasia. Only 7 of 113 (6%) control rats had bone marrow hyperplasia. Such a finding might occur if an animal had leukemia, but no increase in incidence of leukemia was found; the lesions appeared to be associated with an increased demand for leukocytes and erythrocytes in animals with nasal tumors [Ex. 12]. The incidence of leukemia in the 14.3 ppm exposure group was 6 percent with 9 percent in the controls. The incidence of lymphomas in mice was also examined by OSHA; there was no association with formaldehyde exposure.

Extensive hematology data for rats and mice were collected at 6, 12, 18, and 24 months after exposure [Ex. 12]. Measurements included hemoglobin, hematocrit, leukocytes, erythrocytes, mean cell volume, mean cell hemoglobin concentration, reticulocytes, immature neutrophils, mature neutrophils, lymphocytes, eosinophils, and monocytes. In no case was there any statistically significant trend to increasingly abnormal values as exposure continued. These results are consistent with the absence of excess leukemias in the high dose animals.

The brains of animals exposed at 14.3 ppm and of control animals were also examined histopathologically [Ex. 12]. There was no evidence in rats or mice of brain lesions related to exposure to formaldehyde.

Dr. Neil Krivanek of DuPont evaluated information on the CIIT rats to determine if formaldehyde had caused brain damage or brain tumors [Tr. February 15, 1985, pp. 632-633]. According to Krivanek:

At all scheduled sacrifices animals were necropsied and brains were removed and weighed. No differences between exposed and (un)treated animals were found. Brain and spinal cord tissues were examined for both gross and microscopic pathologic changes in high-dose and control animals. Four sections of the brain were evaluated: cerebellum, cerebrum, medulla, and optic nerve.

Simple neurofunctional examinations, such as posture, gait, and pupillary response were performed on all animals prior to scheduled sacrifice at 18, 24, 27, and 30 months in the study. There were no differences found between exposed and control animals. This information coupled with that of the negative histopathologic examinations of nervous system tissue provides strong evidence that formaldehyde does not produce nervous system damage.

Based on this review, OSHA concludes that the CIIT study does not support a finding that formaldehyde

causes brain cancer or leukemia in rodents.

The NYU Study: Studies conducted at NYU [Exs. 42-3; 42-4] corroborate the findings in the CIIT study and demonstrate that the inhalation of formaldehyde induces nasal cancer in rats. The initial study was intended to evaluate the effects of inhalation of bis(chloromethyl)ether (BCME). Hydrogen chloride (HCl) and formaldehyde were premixed before introduction into the chamber air. This approach was supposed to maximize the concentration of BCME, but only small amounts were formed.

Subsequent to the start of the study at NYU, the CIIT announced their interim findings in rats. To follow up on the CIIT findings and compare them with their own results, the NYU investigators conducted a second study containing four groups of animals; one exposed to a premixed HCl-formaldehyde mixture as in the first test, a second exposed to these two gases without premixing, a third group exposed to formaldehyde, and a fourth group exposed to HCl.

All animals, male rats of the Sprague-Dawley strain, were exposed for 6 hrs/day, 5 days a week for life. They were allowed to die naturally or were killed when moribund. Necropsy was performed on each animal, with attention being given to the respiratory tract. In the first experiment, histological slides were prepared from each side of the head. In the second experiment, the head was cut vertically into four slabs beginning just behind the nostrils and extending to the orbits. Histologic sections were obtained from the face of each slab.

In experiment one, the rats were exposed at average concentrations of 14.7 ppm of formaldehyde and 10.6 ppm of HCl. Of the 99 exposed animals, 28 developed nasal tumors which consisted of 25 squamous carcinomas and 3 papillomas. A high proportion of exposed rats showed squamous metaplasia of the nasal cavity. They also had more epithelial hyperplasia and hyperplasia with atypia than the controls. No primary tumors were observed in the larynx, trachea, or lungs [Ex. 42-3].

Although the results of the second experiment were not available in published form, Dr. Roy Albert provided OSHA with information on the incidence of nasal tumors in each of the study groups [Ex. 42-4]. In 100 rats exposed to formaldehyde at nominal concentrations of 14 ppm, there were 39 squamous cell carcinomas, 10 squamous cell papillomas, and 1 fibrosarcoma. When formaldehyde was premixed with 10 ppm of hydrogen chloride, incidences

in 100 rats were: 45 squamous cell carcinomas, 13 squamous cell papillomas, 1 fibrosarcoma, 1 adenocarcinoma, and 1 esthesioneuroepithelioma. If the two chemicals were not premixed, nasal tumor incidences in 100 rats were: 27 squamous cell carcinomas, 10 squamous cell papillomas, 2 adenocarcinomas, and 1 nasal polyp. There were no nasal tumors in 99 air controls, 98 colony controls, or in 99 animals exposed to hydrogen chloride alone.

OSHA concludes that the NYU study confirms in a second strain of rats that exposure to formaldehyde can cause cancer in animals. The Agency is not using the NYU study for quantitative assessment of risk, however, for reasons discussed below.

The first NYU study intended to examine the carcinogenicity of BCME. An esthesioneuroepithelioma was seen, as expected for BCME [Tr. May 5, 1986, p. 162], and HCl, although not irritating when given alone at 10 ppm, could have enhanced the cytotoxicity of formaldehyde. For these reasons, the information in this NYU study is deemed by OSHA to be less reliable as a quantitative evaluation than the CIIT study.

Additional points of concern are: less histopathology was conducted on the NYU rats than the CIIT rats; and interim results were reported only when a tumor was grossly observable. Both factors could result in a failure to detect tumors and a consequent underprediction of risk. Less information is available on experimental conditions and histopathology for the NYU study than for the CIIT study, and the NYU study employed only one dose. Both factors would make any assessment based on the NYU study considerably less reliable than one based on the more extensive CIIT study.

Other Rat Studies: Tobe *et al.* [Ex. 73-146], exposed groups of 32 male Fischer 344 rats to 0.3, 2.0 and 75 ppm of formaldehyde for 6 hr/day, 5 days a week for up to 28 months. The experiment also consisted of a colony control and a room control. In the highest dosage group, there were 14 cases of squamous cell carcinoma and 5 cases of squamous cell papilloma. No tumors of the nasal cavities were observed at 0.3 or 2 ppm. Rhinitis, squamous metaplasia, and hyperplasia of the nasal respiratory epithelium were observed in all three groups exposed to formaldehyde.

Although the Tobe *et al.* study is limited by the small number of animals used, the finding of papillomas is consistent with the NYU study and

suggests that a combination of related tumors, both benign (papilloma) and malignant (squamous cell) is a probable response in experimental studies of inhaled formaldehyde even though the CIIT study reported only the malignant form (squamous cell carcinomas). In contrast, of the three studies in rats, only one, the CIIT study, found polypoid adenomas, suggesting that these tumors may not be reproducible.

The Hamster Study: Dalbey [Ex. 42-33] exposed 88 male Syrian golden hamsters to formaldehyde at 10 ppm for 5 hr/day, 5 days a week, for their lifetime. A control group contained 132 hamsters. At necropsy, "all major tissues" were preserved in buffered formalin. Two transverse sections of the nasal turbinates of each animal were examined along with longitudinal sections of the larynx, trachea, and lung lobes.

Although no tumors were found in either group, survival time of the formaldehyde-exposed hamsters was significantly reduced ($p < 0.05$) compared with unexposed controls. Areas of hyperplastic and metaplastic nasal epithelium were observed in 5 percent of the exposed animals compared with none in the control hamsters.

Some commenters cited the Dalbey hamster study as evidence that formaldehyde does not cause cancer in all species [Ex. 80-261, pp. 56-57; Tr. May 12, 1986, pp. 51-52]. However, the failure to observe tumors in hamsters can be explained by the lower formaldehyde concentration used in the hamster study, the few hamsters used in the study (and resulting low power to detect cancer) and limited pathology. For example, the hamsters were exposed for 5 hours a day, whereas the rats in the CIIT study were exposed for 6 hours per day. If the studies were to be compared, an adjustment to the hamsters' exposure would have to be made. The 10 ppm exposure for 5 hours a day is equivalent to 8 ppm exposure for 6 hours a day. At 8 ppm, the CIIT study predicts about a 2 percent incidence of nasal cancers in rats. Thus, at most only 2 nasal cancers should have been detected in the hamsters. An even lower cancer incidence would be expected in Dalbey's hamster study because of early deaths and limited histopathology. Thus, available evidence on hamsters is judged by OSHA as insufficient to demonstrate differences in species sensitivity to formaldehyde's carcinogenic effects.

Because of serious limitations in the hamster study, OSHA does not regard the information as sufficient to make a conclusion regarding formaldehyde's effects on hamsters. The ability to detect

tumors is dramatically less than for the protocol applied in the CIIT study. Consequently, OSHA also believes that the Dalbey study is not acceptable for making quantitative statements regarding formaldehyde and cancer.

Effects of Sensory Irritation on Breathing Rates: Independent studies [Exs. 42-13; 69-23-A3; 69-23-C4; 70-29; 73-34] show substantial decreases in the amount of air inhaled in certain strains of mice acutely exposed to strong sensory irritants. This decreased minute volume occurs because of reflex inhibition of respiration (reflex apnea).

Unlike the mouse, Fischer and Sprague-Dawley rats exposed briefly to formaldehyde developed only slight changes in breathing rate [Exs. 69-23-C4; 70-19B]. The hamsters response to inhalation of irritant is unknown so it is impossible to determine if the results in hamsters were affected by breathing rate changes [Ex. 139-A-1, Attachment VI, p. 33].

Additional information on breathing changes during subchronic exposures exists for rats. Sprague-Dawley rats exposed to 0, 0.5, 3, or 15 ppm of formaldehyde for 6 hr/day, 5 days/wk for 8 or 16 weeks [Ex. 70-19B], and then challenged with formaldehyde administered by nose piece at 15 or 30 ppm developed depressions of minute volume previously seen in acute studies.

The rats lower respiratory tract responded to the formaldehyde challenge when it was administered by tracheal installation in a different manner [Ex. 70-19B, p. 2]. Reflex apnea, present in the upper respiratory tract, was absent with the lower respiratory challenge. Sensory irritation of the lower respiratory tract was demonstrated, instead, by decreases in both minute volume and tidal volume. Tolerance developed by the end of the exposure period; the authors felt that this tolerance involved compensatory mechanisms different from tolerance seen in the upper respiratory tract.

The finding that mice responded differently from rats when the animals were exposed to sensory irritants, coupled with the finding that these changes do not rapidly resolve, is sufficient to account for the differences in cancer incidence rates seen in these two species. Thus, it is unnecessary to invoke an argument involving differences in species sensitivity to carcinogens to account for differences seen in the CIIT study. Precise estimates of inhaled dose, based on corrections for reflex apnea indicate that the mice exposed at 14.3 ppm actually inhaled approximately the same amount of formaldehyde as the rat exposed at the

intermediate dose, 5.6 ppm [Ex. 69-23-C4].

Cocarcinogenicity and Skin Painting Studies: Several studies, while they do not contribute to the quantitative assessment of risk of exposure to formaldehyde, assist in evaluating formaldehyde's carcinogenic potential. These studies are described below.

In addition to the other experiments described earlier, Dalbey also examined the influence of formaldehyde on the incidence of respiratory tumors induced by diethylnitrosamine (DEN) [Ex. 42-33]. Hamsters received concurrent exposures of DEN and formaldehyde (30 ppm administered for 5 hrs/day in the 2 days prior to each of 10 weekly DEN injections). They developed a higher number of tracheal tumors/tumor-bearing animals at necropsy than those receiving DEN alone. These results indicated that formaldehyde acted to enhance the development of cancers in the respiratory tract.

Spangler and Ward reported preliminary results of a skin cancer study in Sencar mice, a species particularly sensitive to two-stage carcinogenesis [Ex. 70-44]. Solutions consisting of 3.7 to 4.0 percent formaldehyde were applied to the backs of female mice, 30 per group. As an initiator, formaldehyde was administered once. As a promoter, it was applied once or twice a week, positive controls included dimethyl benzantracene for initiation and 12-o-tetradecanoyl phorbol-13-acetate (TPA) for promotion. Negative controls were administered acetone. Formaldehyde was also tested as a complete carcinogen. The preliminary results indicated that formaldehyde, applied to the skin, was probably neither a complete carcinogen nor an initiator in this strain of animals. Interim data on promotion were inconclusive.

Krivanek, Chromey, and McAlack [Ex. 70-43] also examined the potential of formaldehyde to initiate or promote tumorigenesis at the site of contact on the skin of female CD-1 mice. Formaldehyde solutions, in a 50:50 acetone:water mixture, were prepared from paraformaldehyde. TPA was used as a known promoter and benz(a)pyrene (BaP) was used for initiation. Formaldehyde, as an initiator, was applied in a single 5 mg dose followed by applications of promoter, beginning two weeks later, three times a week for 180 days. Formaldehyde, as a promoter, was administered under the same protocol at doses of 1.0, 0.5, or 0.1 mg in 0.1 ml of vehicle. As a complete carcinogen, formaldehyde was applied in an initial dose of 5 mg follow by

periodic exposures of 1 mg administered for 180 days. All animals were observed for 180 additional days after completion of exposure. Skin nodules were considered positive responses if they persisted at least 30 days.

The results of the experiment were as follows for the various initiator/promoter combinations: acetone/TPA-3/29; BaP/TPA 28/29; formaldehyde/TPA 5/29; formaldehyde/acetone-0/30; formaldehyde/formaldehyde-0/30; BaP/1.0 mg formaldehyde-1/30; BaP/0.5 mg formaldehyde-2/30; BaP/0.1 mg formaldehyde-7/30; and BaP/acetone 3/29. The 1 mg dose of formaldehyde was mildly irritating to the skin. Large doses (2 to 5 mg) produced definite skin irritation, so that higher doses of formaldehyde were not considered acceptable. Under conditions of the assay, formaldehyde, at minimally irritating concentrations, did not initiate or promote skin tumors and also failed to act as a complete carcinogen.

While subject to limitations, the two studies on skin tumorigenesis suggest that formaldehyde does not present a cancer hazard by the dermal route when applied to intact skin. Dosage levels were restricted to prevent formaldehyde from damaging the skin, and only a small number of animals was tested. These limitations could make the skin painting studies too insensitive to detect all but a large cancer risk.

The skin painting tests performed for formaldehyde represent classical skin papilloma tests designed to measure cancer promotion. According to the OSTP Report, these tests are more appropriately labeled *in vivo* short-term tests than animal bioassays, and their purpose is not the examination of systemic cancer. Thus, results are not applicable to concentrations of formaldehyde sufficiently concentrated to damage the epidermis. Under such circumstances more formaldehyde would penetrate the skin, and the potential for systemic effects would be greater.

Conclusions Regarding Formaldehyde as an Animal Carcinogen: OSHA agrees with Dr. Roy Albert who stated at the public hearings on formaldehyde:

The evidence is strong that formaldehyde is a carcinogen. It is a mutagen; namely it is capable of attacking the genetic material of cells and producing permanent genetic damage. Ninety-five percent of chemicals that show mutagenic activity are carcinogens.

The explanation for its mutagenicity, that is, its ability to produce irreversible change in the genetic material, DNA, of exposed cells lies in the chemical properties of formaldehyde. It is capable of producing adducts on DNA, crosslinking one strand of DNA to another and crosslinking strands of DNA and protein.

The rat inhalation studies are also decisive in demonstrating the induction of malignant cancers of the rat nasal mucosa and in the nasal mucosa of the mouse to a lesser extent.

This type of cancer bioassay is relevant for humans since the inhalation of bis(chloromethyl)ether, which breaks down to formaldehyde, and which has a similar crosslinking ability as formaldehyde, also produces cancers of the rat nasal mucosa and lung cancer in humans.

Hence, nasal cancer induction in the rat by formaldehyde does not necessarily mean that cancers would be specifically induced in the human nose, but rather that formaldehyde would be a cancer threat to the respiratory tract in humans [Tr. May 5, 1986, pp. 161-162].

OSHA regards the finding of squamous cell carcinoma of the nasal passages in two strains of rats in three independent studies to be extremely strong and reproducible evidence that formaldehyde is an animal carcinogen. Evidence of a dose-response relationship between formaldehyde exposure level and tumor incidence, finding cancers of identical cell type and location in a second species (the mouse), and concordant evidence that formaldehyde is genotoxic increase OSHA's confidence that the squamous cell carcinomas are formaldehyde related. The dose related incidence and severity of preneoplastic lesions at all levels in the exposure treatment groups contribute to the biological plausibility of a neoplastic response (see OSTP Report, Ex. 73-90, p. 8) as does the finding that formaldehyde is capable of interaction with respiratory mucosal DNA (See Ex. 62). In contrast, the failure to find polypoid adenomas except in the CIIT rats indicates to OSHA that the role of the adenomas in assessing risk of formaldehyde exposure is much less certain.

Based on the information cited above, which is basically unchanged since the proposal, OSHA continues to regard formaldehyde as a proven animal carcinogen.

Studies Related to Cancer Mechanisms-Cytotoxicity and Cell Proliferation: Wilmer and coworkers [Ex. 85-107] conducted a subacute inhalation study to determine how dose-rate affects the cytotoxic action of formaldehyde on rat nasal epithelia. Four groups of male Wistar rats, 10 animals per group, were exposed to 5 or 10 ppm of formaldehyde continuously for eight hours a day, or to 10 or 20 ppm for eight 30-minute periods of exposure interrupted by 30-minute periods of nonexposure.

After three days of exposure, the nasal respiratory epithelia of all exposed animals showed a clear increase in cell turnover, measured by the amount of tritiated thymidine

incorporated into DNA. The effect was concentration-related rather than dependent on total dose. Labeled cells were found mainly on the naso- and maxillary turbinates. In animals exposed at 20 ppm, labeling was also seen on the septum and lateral wall. Effects seen after 4 weeks of exposure were similar, but the percentage of labeled cells was less.

Histopathologic changes found in the nose at necropsy after 4 weeks of exposure consisted of: focal thinning and disarrangement of the respiratory epithelium seen in a few rats of the 10 ppm groups and in all animals of the 20 ppm group; squamous metaplasia of the respiratory epithelium often with basal cell hyperplasia in the 10 and 20 ppm groups; degeneration of the olfactory epithelium in the anterior part of the nose in one 10 ppm rat and four 20 ppm rats; and rhinitis in each of the test groups. The authors concluded that "the exposure concentration rather than the total dose of formaldehyde seems to be decisive for its nasal cytotoxicity" [Ex. 85-107, p. 17].

Wilmer *et al.*'s results are consistent with the findings of Swenberg and coworkers at CIIT [Exs. 73-79; 73-81F]. The CIIT investigators exposed Fischer 344 rats and B6C3F1 mice to formaldehyde at 0, 0.5, 2, 6, or 15 ppm for 6 hours a day for 1, 3, 5, or 9 days and measured cell turnover in the respiratory epithelium by labeling DNA with tritiated thymidine. Maximum cell proliferation, a 10 to 20-fold increase, occurred after 3 days in the nasal passages of rats exposed at 6 or 15 ppm and mice exposed at 15 ppm. Three days of exposure of rats to 0.5 or 2 ppm or mice to 0.5, 2, or 6 ppm failed to increase nasal cavity cell turnover.

A single 6-hour exposure of the rats at 15 ppm produced observable cytotoxicity [Exs. 73-79; 73-81F] in regions of the nasal cavity which later exhibited severe degenerative changes [Ex. 73-81F] and ultimately squamous cell carcinoma [Ex. 42-131].

Following 2 days of exposure at 15 ppm, the rats' nasal cavities showed severe and extensive epithelial damage and inflammation with a serofibrinous exudate present over damaged areas. These changes were more advanced after 4 days, with extensive areas of epithelial erosion and ulceration. The cytotoxic damage extended posteriorly along the lateral wall where exfoliating ciliated and non-ciliated cells were located over areas of cellular proliferation and early squamous metaplasia. Cellular proliferation and squamous metaplasia were associated with numerous mitotic figures, altered

cellular orientation, increased cytoplasmic basophilia, and nuclear enlargement. Severe epithelial degeneration with ulceration of the lateral scroll of the nasoturbinate and the adjacent lateral wall occurred after 9 days of exposure. Ulceration was associated with cellular and serous exudate. Similar, but less severe changes were found in rats exposed to 6 ppm of formaldehyde. No epithelial lesions were seen in rats exposed at 0.5 or 2 ppm. The CIIT investigators concluded that the concentration-related cytotoxicity accompanied by increased cell proliferation might be important factors in formaldehyde carcinogenesis [Ex. 73-79].

To test dose-rate effects, the investigators examined cell proliferation in groups of rats exposed to the same total daily dose (ppm/hr), but to different concentrations and durations of exposure [Ex. 73-79]. Exposures were 3 ppm for 12 hours, 6 ppm for 6 hr, and 12 ppm for 3 hours. In the portion of the nasal passages where squamous cell carcinomas were found in the CIIT rat bioassay, cell proliferation was strictly concentration dependent. Cell turnover rates decreased after 10 days, which the authors attributed to the establishment of a hyperplastic response [Exs. 70-23; 73-91E]. These results are remarkably similar to those of Wilmer *et al.* [Ex. 85-107], and they indicate that for exposures of up to 4 weeks, concentration is more important than cumulative dose in determining the extent of tissue damage.

Several investigators have pointed out that the importance of concentration relative to cumulative dose (concentration x time) is not confined to acute studies [Exs. 42-28; 70-23]. Their conclusions are based on a comparison of tissue lesions seen in the CIIT bioassay [Exs. 12; 42-131] and the Biodynamics study [Exs. 42-16; 42-104] where various exposure combinations resulting in approximately the same integrated dose can be compared. For example, rats in the CIIT study exposed at 14.3 ppm (450 ppm-hr/week) for six months had more severe inflammatory hyperplastic and metaplastic lesions than rats exposed continuously in the Biodynamics study for the same time period at 3 ppm (462 ppm-hr/week) [Ex. 42-28]. These studies are described below.

In the CIIT bioassay, gross pathological exams were performed on all mice and rats that died from interim or unscheduled sacrifice [Exs. 12; 42-131]. Histological sections of the nasal turbinates were evaluated for three anatomical levels in the mice and five

levels in the rat and any tissue mass was also evaluated.

Formaldehyde-induced lesions were observed in the epithelial tissue lining the nasal cavity and the proximal trachea. In the 2 ppm rats, squamous cell metaplasia was seen only in the anterior section of the nasal cavity (level I). Incidences were approximately 10, 33, 60, 100, and 20 percent at 6, 12, 18, 24 (end of exposure) and 27 months, respectively. At 5.6 ppm, epithelial dysplasia and squamous cell metaplasia were observed in the anterior section and in the two middle sections (levels II and III). Incidences were highest in level I and least in level III; more animals were affected over time as exposure continued. Three months after exposure terminated, the squamous cell metaplasia partially regressed at all levels.

At 14.3 ppm, a 30 percent incidence of squamous cell metaplasia, seen in Level III at 6 months, increased to 50 percent at 12 months. From 18 months onward, the incidence of squamous metaplasia was about 100 percent in the first three levels. Lesions occurred in the posterior sections (levels IV and V) beginning at 18 months, but they regressed in the posterior levels after exposure ceased.

Biodynamics conducted a subchronic inhalation study to measure the cytotoxic effects of formaldehyde. Cynomolgus monkeys, Syrian golden hamsters, and Fischer 344 rats inhaled formaldehyde at 0.2, 1, or 3 ppm for 22 hr/day, 7 days a week for 26 weeks [Exs. 42-16; 42-104]. Monkeys, like humans, are not obligated to breathe through the nose; several monkeys developed nasal discharge, hoarseness, and cough at 3 ppm. Rats were unaffected; hamsters had a higher frequency of rales, lacrimation, and nasal discharge.

All animals were subjected to gross necropsy, and no exposure-related lesions were found. Electron microscopic examination of the lungs, trachea, and nasal turbinate from 10 rats exposed at 0 or 1 ppm showed no effects. Light microscopic examination performed on the nasal turbinate of all animals, on all gross lesions, and on the lungs and trachea of animals in the 0, 1, and 3 ppm groups showed a possible effect of exposure in the rats. To clarify this point, the investigators examined additional sections and found squamous cell metaplasia of the nasoturbinate with no effect in the ethmoturbinate. Basal cell hyperplasia was observed in the anterior and midportions of the nasoturbinate. More severe effects were seen in the rats exposed at 3 ppm. Hamsters showed no exposure-related

effects, providing the only evidence to suggest that this species may be significantly different from the rat than in its toxic response to formaldehyde. One of the six monkeys exposed at 1 ppm and all six monkeys exposed at 3 ppm developed squamous cell metaplasia and hyperplasia, indicating that primates react to formaldehyde in a manner similar to rats.

Evidence of cytotoxicity has also been demonstrated in humans exposed to formaldehyde. Edling *et al.* [Ex. 85-50] examined the nasal cavities of 20 men exposed to formaldehyde at concentrations ranging from 0.1 to 1.1 ppm for an average of 7 years and compared the results with a group of 25 matched controls. The nasal mucosae of five (25%) of the exposed men were swollen, dry, or both. Histological examination of mucosal biopsy specimens revealed significantly more severe abnormalities in the formaldehyde workers than in the controls even though there were more smokers in the controls than among the exposed (48% vs 35%). The nasal cavities of the formaldehyde workers showed loss of cilia and goblet cells, squamous metaplasia, and in some cases, mild dysplasia. Since factors other than formaldehyde could be ruled out in the study, the authors concluded that suspected precancerous findings might be present in workers exposed to formaldehyde below a TWA of 1 ppm.

Celanese reported to OSHA that their medical surveillance program has not shown sensory irritation in their workers and that examination of the nasal cavities showed no formaldehyde-related effects in operations or maintenance workers. Celanese attributed these findings to its use of a 30 minute STEL of 2 ppm [Ex. 69-33B].

The Celanese results are in contrast to Edling's report where workers developed suspected precancerous changes in their nasal cavities after exposure to formaldehyde [Ex. 85-50]. The inconsistencies in the results of two studies may be related to the extensive examinations conducted on workers in Edling's study, and OSHA considers the implications to be of sufficient severity as to warrant attention.

Conclusions Regarding Cytotoxicity and Cell Proliferation: When cells die prematurely, the organism will attempt to protect itself by stimulating cell replication to replace the dead cells. This process leads to cell proliferation, which may be observable microscopically as hyperplasia. In the case of formaldehyde, this proliferation phenomenon can result in an adverse reaction that enhances the likelihood of

developing cancer. Because formaldehyde and single stranded DNA, present when a cell is replicating, react to form potentially carcinogenic adducts, increases in the rate of cell turnover should increase the amount of cancer found.

The cytotoxic effects seen in the animals' respiratory epithelia also included metaplasia and dysplasia. Metaplasia is a change of one cell to another cell type [Tr. February 13, 1985, pp. 89-110]. Squamous metaplasia occurred at the lowest levels tested in the CIIT rat study, 2 ppm. At higher levels, formaldehyde-induced cancers were seen only in the region of the nose where squamous metaplasia first occurred, suggesting that squamous metaplasia was a precursor lesion in the development of squamous cell cancer. Dysplasia, a disturbance of the normal architecture of the cells [Tr. February 13, 1985, pp. 89-710], is a preneoplastic lesion; the presence of dysplasia also was directly correlated with the development of squamous cell carcinoma in the animals. Although cytotoxicity is not a prerequisite to the development of cancer, cytotoxicity influences the likelihood that cancer will develop. Thus, evidence that cytotoxic effects are occurring is evidence of an increased risk of cancer.

Given the above finding, certain conclusions can be drawn from the data on cytotoxicity and cell proliferation. First, the cytotoxic effects seen in the nasal passages of workers exposed to formaldehyde at concentrations below 3 ppm [Ex. 85-50] are qualitatively and quantitatively similar to cytotoxic changes observed in rats exposed to formaldehyde at 2 ppm. Based on the outcome in rats, *i.e.* cancer, formaldehyde-exposed workers whose nasal passages show evidence of cytotoxicity would be judged as being at increased risk of developing cancer. Thus, workers who are exposed to formaldehyde at levels below 3 ppm as a time-weighted average will be at an increased risk of developing cancer of the nasal cavities. Evidence of cytotoxicity means that such exposures cannot be viewed as "safe".

Second, results in animals exposed to formaldehyde from 2 days to 2 years indicate that cytotoxicity, and hence carcinogenicity, is more closely related to average concentration than to cumulative dose, suggesting that human risk might also be more closely related to average exposure. Thus, estimations of human risk should be based on average exposure rather than on cumulative dose. This finding helps to explain the apparent inconsistency seen

between the human epidemiological data where no dose response relationship was found when risk was measured against cumulative dose and the rodent data which clearly demonstrated a carcinogenic response.

Third, Wilmer *et al.* and Swenberg *et al.* provide evidence of a dose rate effect for cytotoxicity, suggesting that short term excursions well above the average daily exposure concentration will cause greater cell damage, and hence entail a greater risk of developing cancer than would be predicted from risk assessment models which assume that exposure is received uniformly throughout the course of the workday. For example, a time-weighted average exposure of 1 ppm could be achieved by a person uniformly exposed throughout the course of the workday. It could also be achieved by a person exposed at 32 ppm for 15 minutes, clearly a much riskier situation. An even greater risk to the worker exposed to short term bursts of formaldehyde may exist since there is no evidence to suggest that there is lesion recovery over short periods, such as overnight. Clearly a short-term cap on exposure is needed because of the dose-rate effects seen to prevent an excessive risk of cancer development.

Mucociliary Clearance: CIIT researchers [Ex. 70-23] commented that the mucociliary apparatus in the nose functions to impede diffusion of formaldehyde through the mucus layer to the periciliary fluid. This mechanism helps protect the underlying epithelial cells from damage by formaldehyde.

However, formaldehyde can impair mucociliary function *in vitro* and *in vivo* [Ex. 70-23], so that the protection afforded is decreased. For example, when Anderson and Molhave exposed volunteer students to formaldehyde at 0.38 to 1.63 ppm for 5 hours, mucus flow rates in their nasal passages decreased by 10 to 50 percent [Ex. 42-10]. At 1.63 ppm, the ability to detect odor was impaired.

Similar results were reported by Yefremov [Ex. 42-130] who studied 278 employees at Russian wood-processing plants. Rhinopharyngolaryngoscopy revealed pathological changes in the upper respiratory tract in 46.4 percent. Motor function of the nasal mucosa was substantially inhibited in workers compared with controls. This inhibition of ciliary epithelium function was observed in individuals who had no subjective symptoms of disease and in whom no objective pathology was found in the examination.

The effects of formaldehyde on the mucociliary apparatus in the nasal passages of rats have been studied

extensively by the CIIT. The damage observed following *in vivo* exposure to formaldehyde was concentration-related indicating that, as concentration increased, a greater percentage of the formaldehyde inhaled was reaching sensitive target sites [Exs. 25-9; 69-23 E5; 70-23; 73-81F; Tr. February 1985, pp. 259-261].

Rats exposed at 15 ppm developed ciliastasis (beating motion of the cilia stops) on the nasoturbinate; this effect progressed posteriorly along the nose with each additional day of exposure. Rats exposed at 15 ppm also developed impaired mucociliary function (slowing of the mucus flow) on the maxilloturbinate, the lateral aspect of the nasoturbinate, the lateral ridge, and the lateral wall. Progression was most extensive in the first two weeks and only slight during the third week, the maximum time any animal was exposed. Exposure at 6 ppm had focal effects on nasal mucociliary activity in the anterior naso- and maxilloturbinate. Following exposure at 2 ppm, some animals developed small areas of ciliastasis, primarily involving the nasoturbinate. Animals exposed at 0.5 ppm showed no evidence of impaired mucociliary function. The distribution of epithelial lesions (and hence the distribution of nasal tumors in the CIIT 2-year bioassay) was correlated with the distribution of defective mucociliary function, but the investigators believed that mucociliary function was a more sensitive indicator of formaldehyde's toxicity. The authors felt that routine screening of nasal mucociliary function in humans may be a useful tool for detecting early stages of nasal toxicity [Ex. 73-81F, p. 14].

While disturbances in the performances of the nasal mucociliary apparatus may be a factor that helps explain the substantial nonlinear dose-response relationship between formaldehyde exposure and cancer in the rat, OSHA is concerned that diminished function has been observed in humans exposed at levels below the PEL. Results from these volunteers, who received a single 5-hour exposure may not equate to chronic deterioration, which was seen in a group of Russian workers who were more heavily exposed [Ex. 42-130]. This is a possibility that needs further exploration. The human evidence, however, supports the CIIT experimenters belief that alteration of nasal mucociliary function may be a sensitive early warning of potentially harmful exposure.

VI. Risk Assessment

Quantitative Estimates of Cancer Risk

Quantitative estimates of human carcinogenic risk begin with an evaluation of the health effects seen in humans and experimental animals. From this information, studies useful for dose-response assessment are selected. Through the evaluation of such studies, a dose-response assessment is obtained. This dose-response assessment characterizes the relationship between exposure to an agent and the incidence of an adverse health effect to be expected in exposed populations.

Human studies are preferable for quantitative risk assessment but human information is most often not available, or is limited. Carcinogenicity bioassays were originally designed as screening devices, the primary focus being hazard identification, but they are now frequently employed and designed for the quantitative assessment of human risk. In a standard protocol, a limited number of animals are exposed at or near the maximum tolerated dose (MTD) and at another level approximately half the MTD. These levels may be several orders of magnitude higher than the levels encountered by man. As a result, quantitative assessment of human risk based on carcinogenicity bioassays requires two basic extrapolations. The first of these extrapolations is from the high doses used in animal bioassays to the low doses encountered by humans. The second of these is extrapolation from animals to humans. In the case of formaldehyde, a well conducted bioassay was used as the primary basis for the quantitative risk estimates.

Species Selection: In drafting the risk estimate for the proposed rule, OSHA relied on an inhalation study in rats performed by the CIIT. Details of the CIIT study were discussed at length in the proposal [50 FR 50433-50434]. The CIIT study was the largest multiple dose study of formaldehyde conducted in animals. The fact that the CIIT study was properly conducted, using good laboratory practices and a relevant route of administration is uncontested. For example, Dr. John Clary, speaking for the FI, stated [Tr. May 12, 1986, p. 93]:

The response seen in the CIIT study on rats exposed to formaldehyde is a valid response The study was well conducted and the conclusions are valid. It certainly suggests the conditions of that experiment in those animals that formaldehyde has the potential to be a carcinogenic agent.

The appropriateness of the use of the CIIT rat data as a basis of risk assessment was uncontested at the time

of the proposal. Every risk assessment submitted to the record in response to the ANPR employed this information for quantitative risk estimation [Exs. 42-29; 42-31; 45-5; 69-15; 69-23B3; 73-115; 73-149]. The Consensus Workshop on Formaldehyde recognized the clear superiority of the CIIT study; also, the rat data have been used by other government agencies for risk assessments performed in conjunction with regulatory activity [Exs. 42-31; 55-D; 73-149; 114].

Some reviewers however, commented that all data, including that from the mouse and hamster, should be taken into account in assessing human risk from exposure to formaldehyde [Exs. 44-1; 45-1; 80-261, pp. 56-57]. While OSHA agrees that all data should be taken into consideration in making the qualitative determination of carcinogenicity, OSHA believes that only the data that is likely to yield the most accurate assessment of human risk should be used to make quantitative determinations. This is the CIIT rat data. Mathematical extrapolations cannot rise above poor data to accurately predict risk. Thus, studies lacking adequate pathology, having incomplete records, or showing unsatisfactory animal care do not provide an appropriate basis for the estimation of risk.

OSHA reiterates in this final rule the position taken in the proposal that neither the mouse nor the hamster data indicate that the rat is a species peculiarly sensitive to formaldehyde's carcinogenicity (see 50 FR 50435).

There are a number of reasons why the mouse and hamster data, as well as other bioassays, are less suitable for use in assessing human risk. For example, reflex apnea in the mice accounted for the much lower response in mice as compared to the results seen in the rats. Moreover, since workers performing assigned tasks would be unable to reduce their breathing rate in the manner the mice did, the mouse data, uncorrected for breathing rates, are inappropriate for assessing risk to humans.

If a correction for breathing rate differences is made, then the rats exposed to formaldehyde at 5.6 ppm inhaled the same amount of formaldehyde as the mouse exposed at 14.3 ppm. Since the incidence of nasal cancer in the 14.3 ppm mice was the same as that in the 5.6 ppm rats, no additional insight for defining a dose-response relationship to predict human risk is gained by using the mouse data. Therefore, OSHA has not made any separate calculations of human risk based on information in mice. It should be noted, however, that the single

positive data point for the mice falls on the dose-response curve for rats when corrections for breathing rates are made.

The hamster data, obtained as a control group for an initiation/promotion study, are clearly inferior to the rat data for purposes of risk assessment. Few animals were exposed and only one dose was employed. In addition, there were unexplained early deaths, and histopathology was limited compared with that done on the CIIT rats. Limitations in histopathology would underdetect cancers at an early stage of development; this may account for differences in results between the rats and the hamsters.

Substantial background information exists in rats on cytotoxicity, cell proliferation, mucociliary clearance, DNA binding, dose rate effects, reflex apnea, and the progression of lesions. The exposure concentrations used to derive these data were identical to those in the CIIT bioassay. This information assists in making decisions on risk, but it is limited for mice and nonexistent for hamsters. Consequently, the hamster represents the species least likely to yield information on a human's risks associated with exposure to formaldehyde; even for the mouse, much valuable information is not available.

Various criticisms have been made of the other studies which might have been used in assessing human risk. For example, with regard to the Tobe *et al.* rat study, the FI pointed out several limitations:

There are a number of problems with this study, including the small number of animals studied, questionable experimental controls and inadequacies in analytical techniques and sampling methods for formaldehyde [Ex. 77-19a, Att. 16, p. 1].

OSHA agrees that this study is less appropriate for assessing human risk than the CIIT rat study, which was more carefully controlled. The Tobe study results are consistent, however, with the results from the CIIT rats (44% incidence of squamous cell carcinomas in the high dose group vs 43% in the 14.3 ppm CIIT rats), so that estimates of human risk predicted from the Tobe study would be in line with the estimates made from the more acceptable CIIT rat data except to the extent that experimental limitations in Tobe *et al.* confound the results. The small number of animals, lack of experimental detail and backup data regarding laboratory audits, and questions raised regarding animal husbandry lead OSHA to conclude that an independent assessment of human risk based on Tobe *et al.* is not warranted.

The NYU data have been rejected for risk assessment by the EPA and the CPSC because only one dose was administered [Exs. 42-31; 73-149] greatly limiting the ability of the information to predict low-dose risk. (Low-dose estimates of human risk from the NYU data would be higher than those predicted from the CIIT study since a linear model would have to be employed to estimate risk.)

Although it would be possible to derive low-dose estimates of human risk on the basis of the NYU data and compare this information with estimates from the CIIT data, OSHA does not endorse this approach. Because the NYU study involves a single experimental dose, only a linear model can be fitted to the data. All other data available from extensive animal testing indicate that a linear model is not an adequate description of the dose-response relationship for formaldehyde exposure and cancer incidence. Thus, OSHA believes that the NYU data should not be used for purposes of defining a dose response curve for quantitative risk assessment because little confidence could be placed in such estimates.

Interim results from the NYU study for the formaldehyde-only (without HCl) exposure group found only 10 nasal cancers in 100 rats [Ex. 42-4] which might appear to be at odds with the results seen in the CIIT rats. Final results [Ex. 42-3], which were not published, however, indicate a 39 percent incidence of squamous cell carcinomas and a 10 percent incidence of squamous cell papillomas in the NYU study as compared to a 51 percent incidence in comparably exposed CIIT rats still alive after the first tumor was diagnosed. This is a remarkably similar finding given the differences in strains used, histopathological techniques, and experimental variables. The results of the NYU study, like the Tobe *et al.* study, fall on the dose-response curve derived from the CIIT rat study. Thus, the results from the three independent studies of rats show great reproducibility; this gives OSHA confidence that the figures derived from the quantitative risk assessment based on the CIIT rat study are reasonably representative of results obtained from other studies and are clearly reliable estimates.

Combining Data From Several Studies: One commenter combined the results from a number of studies in different animal species to define a dose-response curve [Ex. 80-261, pp. 57, 74]. As described below, this approach was soundly criticized by participants in the rulemaking. OSHA agrees that

results of different experiments conducted under different protocols should not be combined.

Because of experimental variables, different studies are never equally sensitive in their ability to detect a carcinogenic response. Each study is limited in its ability to detect tumors by the extent of the histopathology conducted, and therefore animal studies may underestimate true tumor incidence. Thus, as prudent public policy and sound science, OSHA must choose sensitive studies for use in quantitative risk assessment.

Dr. Schneiderman, who assisted in preparation of an earlier risk assessment for OSHA [Ex. 42-29], discredited the idea of combining data from several studies to derive a single dose-response curve:

If you add up responses at a given dose in one animal species and add them to responses at a given dose in another animal species, I think that is nonsense * * *. It seems to me that what you do is engage yourself in an arithmetic exercise, and you've disregarded the public health consequences of what you are doing. I would be shocked if someone who knew what he was doing proposed this seriously [Tr. May 7, 1986, p. 141].

Dr. Albert, the senior investigator for the NYU rat study, stated:

I think the pooling of the rat and mouse data done by the same group would be less objectionable than pooling the rat, mouse, and hamster data where the hamster data was done by a different laboratory and the director of that laboratory has some very serious reservations about that study involving poor survival.

Dr. Albert further commented that even though a single laboratory conducted both mouse and rat studies, he believed it would be inappropriate to pool the single laboratory's results because of the mouse's ability to hibernate when exposed to irritants [Tr. May 5, 1986, pp. 178-179].

Dr. Frederica Perera, a cancer researcher testifying for the Natural Resources Defense Council, stated:

I see no point in that [combining the various animal groups to use in risk assessment] at all, because you are dealing with different species, different strains, and different exposure conditions, often different routes of exposure. I think what you do is you take your best bioassay, the bioassay that is well-conducted, conforms with [good laboratory practices] GLP, and so forth * * * and you use those [results] * * *. For purposes of risk assessment you use the most sensitive animal responding. So I see absolutely no reason for combining data from positive and negative studies for this purpose. I don't think there's any rationale for doing that * * *. Combining even cross-positive studies, you have the same thing, you have

the same variability [Tr. May 15, 1986, pp. 201-202].

There are important reasons for conducting tests for carcinogenicity of a chemical in more than one rodent species. Dr. Edward Fairchild elaborated on these reasons and the implications to ascertaining human cancer risk from animal data in an article entitled "Guidelines for a NIOSH Policy on Occupational Carcinogenesis" [Ex. 144-I, p. 202]. According to Dr. Fairchild:

[T]he recommended protocol has been to conduct carcinogenesis tests in at least two species. The intent of these recommendations clearly was that of decreasing the chance of false negatives that could result from a test in a relatively resistant species for a given test substance * * *. If positive carcinogenesis [is] obtain[ed] with adequate and reproducible tests in the one species, then these results clearly stand on their own merits and cannot be made less valid by the fact that the results [are] not obtain[ed] with another species.

Multiple species are tested to improve our ability to detect those chemicals that are hazardous which increases our confidence in extrapolating these findings to humans. Thus, if the hamster data are negative and the rat data are positive, the relevant information is from the rats. Information available from a resistant species or from an inadequate study does not contribute to the ability to identify a carcinogen or to predict associated risks due to exposure.

As pointed out by Dr. Fairchild, multiple testing leads to greater confidence in the ability of the animal studies to predict human cancer risk. Combining data from a resistant species with other data to predict human risk is inappropriate, however, because it is likely to result in the underprediction of human risk. For formaldehyde, the consistency in results obtained in the three independent tests of rats indicates that the results are reproducible, and therefore form a suitable basis for the assessment of risk.

In general, the approach most likely to lead to accurate predictions of low dose risk is the selection of the best study available. This is not to say that the best evidence is that which predicts the greatest risk, although this is often the case.

After the data to use for risk assessment is selected, other data may be used quantitatively, as well. Such information can be useful in describing the degree of confidence to be placed in the assessment. In exceptional circumstances where no one study is adequate to describe the dose-response curve, results from more than one study

might have to be combined. Under such circumstances, there is much less confidence in the dose-response relationship generated. OSHA does not believe that such an assessment is warranted for formaldehyde.

Conclusions Regarding Animal Data for Risk Extrapolation: After carefully reviewing all testimony presented to the Agency, OSHA believes that the CIIT study on rats provides evidence that formaldehyde demonstrates carcinogenic activity in mammals and that this study alone should be used to extrapolate the results of animal data to humans. Results from the CIIT mouse study and the NYU and Tobe *et al.* rat experiments corroborate these findings but are less reliable predictors of risk associated with formaldehyde exposure because of limitations imposed by their experimental designs; therefore the information in these studies as well as Dalbey's study of hamsters should not be used to perform alternative quantitative assessments of human risk. If quantitative risk assessment were conducted based on the NYU or Tobe *et al.* results, the malignant tumors seen in these studies have a benign counterpart which should be included in the assessment. The NYU and Tobe, *et al.* studies would be expected to yield higher, but less accurate predictions of low dose risk in humans.

The various rodent studies are substantially different in important points such as survival rates and amount of pathology conducted, so that they are not cross-comparable. Under these circumstances, it would be inappropriate to combine the results of several investigations to perform a quantitative risk assessment for humans. The largest study conducted in a sensitive species, the CIIT rat study has the most extensive pathologic evaluation. In addition, there are also numerous studies containing information related to cancer mechanisms that were conducted at the same doses as the CIIT study. Taken together these factors lend confidence that the CIIT rat study is the one animal study most likely to adequately predict human risk.

Corrections for Early Death: In a bioassay, animals are often sacrificed at intervals to examine the progression of lesions. Under such circumstances, all of the animals are not equally at risk of developing cancer, and some correction for early deaths may be needed to use the animal data in the quantitative assessment of risk. The effects of corrections for early deaths were discussed at length in the proposal [50 FR 50449-50463].

Several methods have been employed for modification of the CIIT rat data on tumor incidence to correct for early deaths and serial sacrifices. At the extremes, one assessment assumed all animals to be at risk [Ex. 45-5]; another assessment used only animals killed at 24 months [Ex. 69-15]. Other corrections included: the exclusion of all animals dying or killed before the first tumor was found at 11 months; the prorating of each rat's lifetime so that it contributes to the risk estimate only the portion of the expected average lifetime actually lived; and exclusion of all animals dying or killed before 24 months even though some had developed nasal cancer. While all of these methods are somewhat artificial, errors contributed by corrections for sacrificed animals appear very small compared to other errors that might be introduced [Ex. 45-5].

Dr. Robert Sielken performed an analysis using three separate methods to adjust for early deaths of the CIIT rats [Ex. 45-5C]. The number of rats at risk in the three assessments was determined to be: (1) All non-sacrificed rats (2 cancers/160 rats at 5.6 ppm and 87 cancers/160 rats at 14.3 ppm); (2) rats not sacrificed at 6 or 12 months (2 cancers/200 rats at 5.6 ppm and 93 cancers/200 rats at 14.3 ppm); and (3) all rats (no cancers in 237 control animals, none in 238 rats exposed at 2 ppm, 2 cancers/235 rats at 5.6 ppm, and 103 cancers/224 rats at 14.3 ppm). All three methods yielded essentially the same dose-response curves as long as the same number of stages was used in the mathematical model employed.

In an analysis conducted for OSHA, Siegel *et al.* [Exs. 42-29; 42-109] adjusted for early death by defining the number of rats at risk to include those killed or dying after the appearance of the first squamous cell carcinoma at 11 months. This gave tumor incidences of 0/216, 0/218, 2/214, and 103/200 at exposure concentrations of 0, 2, 5.6, and 14.3 ppm, respectively.

CPSC [Ex. 42-31] eliminated all rats sacrificed at 6, 12, and 18 months and any animals whose nasal cavities were not histopathologically examined. This led to corrected cancer incidence data of 0/157, 0/159, 2/155, and 95/145 at exposures of 0, 2, 5.6, and 14.3 ppm, respectively. A similar assessment was performed by K.S. Crump and Co., Inc. [Ex. 138-C, pp. 137-138].

The ORA assessment [Ex. 43] eliminated animals killed before 24 months, animals whose nasal cavities were not histopathologically examined, and animals dying before the first cancer was observed at 11 months. This

led to corrected carcinoma incidence data of 0/156, 0/159, 2/155, and 95/145 for exposures of 2, 5.6, and 14.3 ppm, respectively.

In calculating the effective number of rats-at-risk, EPA in a draft risk assessment [Ex. 73-149] (final version published after close of OSHA's formaldehyde record) concluded that rats dying before the first cancer was identified at 11 months were not at risk. Rats sacrificed at 12 and 18 months were handled as if they would have responded the same as those that remained alive after the sacrifices. This approach yielded corrected data of 0/156, 0/159, 2/153, and 94/140 at dosage levels of 0, 2, 5.6, and 14.3 ppm, respectively.

Drs. Charles Brown [Ex. 55-A7] and David Gaylor [Ex. 55-A24] pointed out that EPA's approach for correcting for early deaths probably biased the results toward underestimation of risk. This bias would occur because a disproportionately large amount of the risk occurs at the end of the lifespan with a correspondingly lower risk in young animals.

Based primarily on Sielken's assessment [Ex. 45-5C], OSHA concludes that determination of the best approach to define the number of rats-at-risk is not a critical step in determining excess risk from exposure to formaldehyde, and OSHA has not attempted to standardize various authors' approaches to a single method for comparison of the results.

Modeling the Dose Response Curve: Because of the complexity of the carcinogenic process and the fact that so little is understood about the pathogenesis of cancer, there is uncertainty in describing the shape of the dose-response curve for carcinogens when data from high doses are used to predict risk at low doses. In general, there are usually no data points in the low-dose region to aid in defining the curve. Hence, investigators turn to mathematical models in an attempt to explicitly characterize the unknown relationship between exposure and response in regions not experimentally verifiable. The risk estimation process also places an upper bound on this dose-response relationship in the low-dose region [Ex. 73-90, p. 80].

Several mathematical models available for risk assessment can adequately predict the shape of the dose-response relationship for formaldehyde in the region of the observed experimental data. At low doses, the behavior of different families of models may vary. Present circumstances do not provide adequate

information to identify any set of parameters for a single model as the correct expression of formaldehyde's carcinogenicity. Therefore, OSHA has examined information on a number of models and looked at a range of estimates. There are four families of models employed to predict low dose risk from experimental data. These are tolerance distribution, mechanistic, time to response, and pharmacokinetic models. OSHA has information available on low dose risks of formaldehyde for each of the families of models (see 50 FR 50457-50460), and they show a wide range of low-dose risk estimations, varying over 14 orders of magnitude [Ex. 61].

In some circumstances a model can be excluded as biologically implausible or mathematically flawed. Otherwise, the estimates from the various models reflect uncertainties introduced by selection of the model. For its final assessment of risk, however, OSHA has chosen to apply a single model which is reasonable, biologically plausible, and based on accepted theories of carcinogenesis.

While there are uncertainties in the extrapolation of the risk of cancer from high doses of formaldehyde to low doses, confidence in the estimate of risk is increased when the experimental data used to predict risk are close to the range of interest and they are consistent with the experience of humans who have been exposed to formaldehyde at low doses. The old 3 ppm PEL falls within the range of data from animal bioassays, and consequently, the risks predicted by the various models show little variability at 3 ppm. At lower concentrations where no data points are available, the various mathematical models give a wider range of predicted risk.

The wide range of estimates for low-dose risk that result from the various mathematical models "may be traced back to the basic inadequacy of the formaldehyde bioassay data relative to the problem of low dose extrapolation" [Ex. 63, p. 749]. As Starr and Buck pointed out, allocating enough animals to the 5.6 ppm exposure group to yield a statistically significant incidence of cancers and using a fourth exposure group somewhere between 5.6 and 14.3 ppm would have enabled researchers to more accurately predict low-dose risk [Ex. 63, p. 749]. While the tumor incidence data provide a good characterization of the median dose, they provide virtually no information regarding dispersion about that dose. The tolerance distribution models are

particularly vulnerable to this deficiency in the formaldehyde data.

Tolerance Distribution Models: These models assume that each member of a population has a threshold level below which that individual will not respond to the exposure in question. Variability among individuals affects the results, so that the experimental data can be described in terms of a probability distribution. Two commonly employed tolerance distributions, the probit and logit models describe the statistical variations of the study population. Each model assumes a different probability curve to describe the individual variability observed within a population.

The probit model assumes that the logarithms of each response are normally distributed about a mean. This model was initially developed for drug standardization in which responses generally fell in the range of 5-95 percent. It was not particularly designed to fit data outside this range, and the zero response for this model is approached much more rapidly than for other mathematical models presently used in low-dose risk assessments.

At one time the Mantel-Bryan procedure, which employs a probit model, was used extensively for estimation of low dose risks. According to the OSTP report [Ex. 73-90], subsequent research has shown that the probit model tends to produce estimates that are much more likely to underestimate risk than other models, and its use in quantitative risk assessment has markedly declined.

The many orders of magnitude of difference in assessing risk of formaldehyde exposure at low doses was caused primarily by use of extremely low estimates derived from the probit model. The probit model also produced estimates which are now known to be most out-of-line with known human risks from exposure to formaldehyde. Thus, OSHA rejects the use of risk extrapolations for formaldehyde based on the probit model.

The logit model is similar to the probit model in that it leads to an S-shaped dose-response curve, but low dose estimations approach zero much more slowly than they do for the probit model, and this model gave risk estimations from animal data that were more in line with estimates derived from mechanistic models.

The Weibull model is based on a distribution compatible with the assumption that cancer begins in a single cell, that individual cells in a tissue behave independently, and that

cancer begins when the first cell in a tissue becomes cancerous [Ex. 175-4, pp. 15-16]. As a tolerance distribution model, the Weibull model, with an assumption of an independent background, predicts excess risk at low doses in the same way as the logit model. The Weibull model can also be used as a time-to-tumor model if one of its parameters is interpreted to represent the "latent" period between exposure and manifestation of a tumor.

In the proposal [50 FR 50452], OSHA examined tolerance distribution models, including the Weibull model, and concluded that they are less biologically meaningful representations of the carcinogenesis data on formaldehyde than the multistage model. As OSHA's proposal indicated, the process leading to carcinogenesis for formaldehyde does not appear to proceed as a single event, although each group member probably has an individual tolerance level which will lead some members to respond more rapidly than others. Instead, the data show a complex series of events, all of which influence cancer response (see 50 FR 50452). For example, CIIT rats kept 3 to 6 months after termination of exposure showed regression of "preneoplastic" lesions implying that cells may undergo a series of reversible transformations before becoming cancerous. To describe such a phenomenon, a model should be stochastic (*i.e.* the cell does not act independently of past events). Tolerance distribution models are not stochastic and cannot be adapted to describe known biological mechanisms thought to lead to cancer from formaldehyde exposure. Therefore, OSHA concludes that tolerance distribution models may not describe the risk of cancer from formaldehyde exposure appropriately, and OSHA has not relied on tolerance distribution models in its quantification of risk.

Mechanistic Models: These models consist of the one-hit, the multistage, and the multihit models. These models derive from the assumption that a tumor originates from a single cell that has been damaged by either a chemical or one of its metabolites [Ex. 73-90, p. 80].

The simplest mechanistic model is the one hit model which assumes that a tumor results from a single chemical hit [Ex. 175-4]. This model contains only a single parameter other than background and it does not provide an adequate fit to the highly non linear dose-response data on squamous cell carcinomas in the rat nasal cavities.

The multihit model is a generalization of the one-hit model. It assumes that the target cell must undergo at least a

defined number of chemical hits before the cell can achieve its carcinogenic potential. According to the OSTP report [Ex. 73-90, p. 81], some investigators regard the generalized multihit model as more flexible than the multistage model, but research results indicate a number of practical problems associated with its application, such as indications of "safe doses" at levels higher than doses that have actually produced deleterious effects [Ex. 73-90, p. 81].

Although the multihit model had been recommended by the Food Safety Council in 1978 for use in risk assessment, others now criticize the multihit model because it can manufacture a background rate even when there is no evidence in the data to support such a rate [Ex. 175-4, p. 22]. When the dose response curve is concave, the model may produce estimates of safe doses that are unrealistically low so that low-dose risk is over-predicted. For these reasons, OSHA has not considered estimates of risk based on the multihit model in its quantification of risk of formaldehyde exposure. However, when certain corrections are made, some of the problems associated with the multihit model are less likely to occur, leading to results comparable with those from the multistage model [Ex. 175-4, p. 22].

The multistage model of Armitage and Doll, as modified by Crump, is the most widely applied of all low-dose extrapolation models [Ex. 73-90, p. 80]. This model is based on the observation that a tumor goes through several different stages of development. Before the tumor is clinically detectable, each stage may be influenced by various carcinogens. Estimates of low-dose risk can be calculated in two manners; *i.e.* by assuming that the probability that a tumor will occur is a function of the probability that it is caused by background and the probability that it is caused by the carcinogen in question, or by assuming that the probability that a tumor will occur is based on the probability that it is caused by background, by the carcinogen in question, and by interactions between background and the carcinogen. As presently constituted, computer models based on the multistage model apply Abbott's correction to express the interaction between the carcinogen and background. Consequently, background rates become important at low doses and some predictions of cancer risk based on the multistage model tend to be relatively more conservative than estimates from other models.

Abbott's correction for the interaction between the carcinogen and background

assumes that the two responses are independent. It does not account for the possibility of synergism. If various exposures to formaldehyde and other carcinogens present in the general environment contribute synergistically to the same chain of events leading to production of a tumor, the maximum likelihood estimate (MLE) for the multistage model based on animal data will not correct for this additional risk. Consequently, some groups prefer to use the upper confidence limit (UCL) because it is less likely to underestimate human risk.

In previous quantitative risk assessments based on experimental animal data, including several risk assessments for formaldehyde, OSHA and others have consistently shown a preference for the multistage model of carcinogenesis. In addition, EPA's Guidelines for Carcinogen Risk Assessment specify the selection of the linearized multistage procedures for estimating human cancer risk from animal evidence [Ex. 73-149].

The California Health and Welfare Agency concluded that, in general, the multistage model is an appropriate method for dose extrapolation (cited in Ex. 175-4, p. 34), but they pointed out that the multistage model might be inappropriate when empirical data indicate a dose-response curve of a "quasi-threshold" type, flat for two or three dose levels and then curving sharply upwards. In these circumstances, certain ways of applying the multistage model can underestimate the number of stages and overestimate the low-dose risk (cited in Ex. 175-4, p. 34).

The limited data from the CIIT rats, *i.e.* four data points, suggest that formaldehyde might possess such a "hockey stick" dose-response relationship. When non-negativity constraints on the multistage coefficients are applied to such data using a classical statistical approach, the number of degrees of freedom must be restricted to the number of dose groups minus 1 [Ex. 138-C, p. 144]. Because of these underlying statistical assumptions, the maximum number of stages that can be predicted from the CIIT rat data is three. For formaldehyde, Global 79, a computer program that mathematically expresses the multistage model, predicts a 3-stage model with one parameter, $q_3 = 2.3 \times 10^{-4}$ for the maximum likelihood estimate (MLE) and $q_1^* = 1.1 \times 10^{-3}$ for the upper 95th percentile confidence limit (UCL) [Ex. 42-29, p. 91]. When a dose-response curve is derived from the incidences at 5.6 and 14.3 ppm, the model is unable to

predict a function with sufficient curvature to closely fit the data at 2 ppm, and thus tends to predict higher low-dose risks than the apparent "hockey stick" dose-response curve seems to indicate. This problem can be addressed in the computer program, Global 82, which does not necessarily restrict the number of stages. Global 82 generated a dose-response curve for formaldehyde based on a five-stage model, which provides a statistically adequate fit to all of the CIIT rat data [Ex. 43]. This five-stage model seems to provide a better description of the dose-response curve for formaldehyde. However, the three-stage model is also appropriate because it does not violate conventional statistical methods as the 5-stage model does. The three-stage model may also be appropriate for biological reasons: cellular changes seen in the rats' nasal cavities when they were exposed at 2 ppm indicate that this is not a "no-effect" level, as the 5-stage model assumes, but simply a level where the predicted incidence of cancer is too low to be detected in a study of the size conducted.

The equations generated by these computer models show various stages of action in the multistage model. They are, however, based solely on mathematical fit to known data points. While the coefficients and the stages represented have a theoretical basis, it is unknown whether either the 3-stage or the 5-stage model reflects underlying mechanisms related to formaldehyde's ability to produce a malignancy. As summed up by Dr. Schneiderman, who assisted in development of the quantitative risk assessment prepared by Clement Associates for OSHA (See Ex. 42-29):

I think right now in terms of our knowledge of carcinogenesis, the multistage theory *per se* is appropriate. But in terms of the number of stages, I don't think we really know enough to put this together [Tr. May 7, 1986, pp. 142-143].

Time-to-Tumor Models: Another class of models employed in low-dose extrapolation is the time-to-tumor model. These models attempt to describe the complex relationship between dose, tumor latency, and cancer risk. There are two risk assessments based on time-to tumor models in OSHA's formaldehyde record; an assessment that uses a Weibull model to reflect time and a multistage model to describe effect, performed by Crockett and Crump for the EPA [Ex. 69-23 B-3], and another assessment by Sielken [Ex. 45-1] based on the Hartley-Sielken model.

Regarding time-to-tumor models, the OSTP Report observed:

While time-to-tumor models can lead in many instances to a more complete characterization of the underlying carcinogenic process, the quality of available data may not permit their application or, at the very least, is often not sufficient to allow any discrimination among such models using goodness-of-fit criteria. Furthermore, a recent analysis of a simulated data base containing information on time-to-tumor occurrence indicated that low-dose risk estimates generated by a variety of extrapolation procedures occasionally differed from the actual risk by three orders of magnitude even when this additional information was included in the modeling process [Ex. 73-90, p. 81].

The OSTP report concluded that, on the whole, incorporation of time-to-tumor data does not substantially increase the precision of low-dose risk estimation relative to modeling based only on quantal response information [Ex. 73-90, p. 81].

For formaldehyde, time-to-tumor models submitted to the record do not predict similar risks; the results differ much more than the results from various analyses based on the multistage model. Crockett and Crump [Ex. 69-23 B-3] predicted maximum likelihood estimates (MLEs) based on time-to-death from tumor of about 740 per 100,000 for exposure at 2 ppm, 71 per 100,000 at 1 ppm, and 15 per 100,000 at 0.5 ppm [Ex. 69-23 B3]. Sielken predicted that 4 cancers per 100,000 will occur at 2 ppm, 0.3 per 100,000 at 1 ppm, and 0.05 per 100,000 at 0.5 ppm [Ex. 45-5]. At 0.5 ppm, Crockett and Crump's estimate exceeds Sielken's estimate by a factor of 300, and at 2 ppm the estimates are larger by a factor of 185. The disparities in the results predicted by the models appear primarily to be expressions of the authors' conclusions regarding the best methods for application of animal data to the assessment of risk. These two investigators also differed greatly in their assessments based on conventional multistage analysis. Corresponding MLEs predicted by Sielken from the multistage model yielded estimates of 20 cancers per 100,000 at 2 ppm, 0.9 per 100,000 at 1 ppm, and 0.06 per 100,000 at 0.5 ppm. Lifetime risk estimates (MLEs) calculated for OSHA by Clement Associates using Crump's multistage model were: 184 per 100,000 at 2 ppm, 78 per 100,000 at 1 ppm, and 23 per 100,000 at 0.5 ppm.

In the proposal [50 FR 50453] OSHA discussed some advantages to time-to-tumor models. For example, at 1 ppm, time-to-tumor modeling demonstrated that the risk resulting from exposure for half of a rat's lifetime was equal to only 1/4th the risk of exposure for a full lifetime [Ex. 45-1]. This finding has

important implications for human exposure and for the significance of reducing an employee's exposure even though higher exposures have occurred in the past. EPA, however, has rejected time-to-tumor models for formaldehyde because of difficulties in dealing with sacrificed animals [Ex. 73-149]. No additional information regarding time-to-tumor models was received by OSHA from the public comments or the hearing testimony. The CIIT representative, Dr. Starr indicated that the CIIT is reviewing the original rat data in order to assign an exact cause of death for each animal [Tr. May 9, 1986, p. 141]. This information, which should improve the quality of the underlying data needed for time-to-tumor models, may increase the ability of such models to predict low dose risk of formaldehyde exposure. At present, however, time-to-tumor models do not increase the accuracy of predictions of low-dose risks of formaldehyde exposure made by quantal models, and may even be less accurate. Therefore, OSHA concludes that the use of risk assessments based on time-to-tumor models is not preferable at this time.

Pharmacokinetic Models: Many carcinogens require activation to reactive metabolites before they are capable of interacting with DNA and initiating the carcinogenic process [Ex. 56, p. 2]. After absorption into a cell, the chemical can be activated to a reactive metabolite which can be detoxified, excreted, or bound to DNA [Ex. 56, p. 6]. The processes leading to distribution and metabolism of chemicals in some cases are known to be nonlinear, and some metabolic pathways are capable of saturation, especially at the high doses used in animal bioassays. Pharmacokinetic models attempt to use this information to develop mechanistic models to estimate the risk of developing a disease [Ex. 56, p. 2].

Gehring and Blau developed a pharmacokinetic model that attempts to determine the effective dose of the ultimate carcinogen at the site of the genotoxic lesion [Ex. 56, pp. 2-3]. Hoel *et al.* [Ex. 69-23 B4], using this concept, developed a model that presumed that the process leading to delivery of the carcinogen to the target site was a nonlinear process that could be approximated by measurement of DNA adduct formation at the target site. Hoel's model was applied to formaldehyde by Starr and Buck [Ex. 63]. (Starr and Buck's analysis and data underlying the analysis are described at the end of the risk assessment section).

A feature of pharmacokinetic models which has attracted considerable attention, especially for formaldehyde,

is that under certain circumstances they predict a quasi-threshold or "hockey-stick" dose-response relationship. According to Paxton *et al.* [Ex. 56, p. 4]:

These pharmacokinetic models . . . have not been accepted as valid for general use because they tend to be considerably less conservative than the currently accepted low-dose extrapolation models without having been demonstrated to be biologically accurate.

Because formaldehyde, itself, is probably the biologically active agent, it is questionable whether the basic structure of pharmacokinetic models is appropriate for estimating risk from formaldehyde exposure.

OSHA's Conclusions Regarding Dose-Response Models: Because the multistage model is based on a theory that most accurately describes what is known about formaldehyde's carcinogenic activity, OSHA believes that this model is most likely to provide a valid description of the dose-response curve for formaldehyde. Certain other dose response models cannot be ruled out completely; these include the multihit model assuming additive background and possibly the logit and Weibull models, although these tolerance distribution models cannot take into account the potential for two carcinogens to act together to enhance each other's effects. As can be seen in the preamble to the proposal [50 FR 50457-50460], risk estimates using these other models do not vary widely from the 5-stage multistage model, indicating that the dose response curve derived from this model provides relatively consistent predictions of risk for exposure in the range of the 1 ppm PEL.

OSHA's decision to employ the multistage model is not influenced by the controversies surrounding the use of the pharmacokinetic model. The pharmacokinetic model relies on several controversial assumptions. As Paxton *et al.* pointed out, the model implicitly assumes that formaldehyde has no effect on any stage in the development of cancer following its initial interaction with DNA [Ex. 56, p. 11], which is not consistent with existing information on formaldehyde. In terms of the actual mathematical model used to predict the dose response curve once the dose and response are defined, both OSHA [Ex. 43] and Starr and Buck [Ex. 63], who employed a pharmacokinetic approach, used the Armitage-Doll multistage model.

Assumptions Concerning Background Risk: All of the mathematical models but the Armitage-Doll multistage model describe the effect of a single toxic agent. Multistage theory permits

consideration that two or more carcinogens acting together might be able to enhance each other's effects [Ex. 16, p. 60]. This does not come into effect simply because exposure to two different agents causes a higher response than one agent by itself; the increased response attributable to one agent must be altered by the presence or absence of others. The concern is that small doses, which individually are safe, may act together to produce an unacceptable risk. This concept underlies the Armitage-Doll equation, although existing computer models assume that all of this interaction is described as "background."

The assumption that the test agent and other factors causing the same type of tumor might multiply each other's effects is appropriate whenever the test agent shares a mechanism with at least one of the agents also producing a response. If even a small portion of the background incidence is associated with the same mechanistic process as the toxic chemical, the multistage model becomes essentially linear at low doses [Ex. 73-90, p. 8]. Discrimination between additivity and independence is difficult because the shapes of dose-response curves in the observable range are generally unable to distinguish between the two assumptions. However, behavior in the low-dose region may be quite different.

Many investigators assume that there is an interaction between the carcinogen and processes that give rise to a "background" incidence of cancer. Exceptions to this general assumption are made only when the mechanism of action of the carcinogen is distinct from the mechanisms of action for other relevant carcinogens (cited in Ex. 175-4, p. 33), a condition not applicable to formaldehyde. Evidence in the formaldehyde record, such as the information showing that exposure to several nasal carcinogens, including formaldehyde, leads to a synergistic or enhanced risk (see epidemiology section), clearly shows that formaldehyde can interact with other carcinogens.

Dr. Perera cited additional evidence that formaldehyde's effects occur, not in isolation, but through interaction with other ongoing processes.

Linearity at low dose for formaldehyde is supported by the demonstrated toxicity of the compound and the ability to interact with other mutagens [and] carcinogens in enhancing their DNA-damaging, mutagenic, or carcinogenic effects.

Because of this, Dr. Perera indicated that risk estimates based on the multistage model should be the Upper confidence

limit (UCL), rather than the Maximum likelihood estimate (MLE), so as to not underestimate risk [Tr. May 15, 1987, p. 95].

A potential error in estimating extra risk from the multistage model can occur when no background incidence was found for the tumor in question in control animals in the bioassay. In any animal bioassay, reported tumor incidence rates are influenced by the number of slides that can reasonably be prepared for evaluation by a pathologist. There is a further practical limit as to the number of animals that can be handled in a single experiment. Hence, tumors that occur very rarely in animals are likely to be undetected in individual experiments [Ex. 69-15].

Information on historical controls may also not provide a reliable estimate of background incidence. A few years ago most investigators did not section the nasal cavities; currently, the nasal turbinates are routinely examined histologically. As a consequence, spontaneous tumors are now being reported where they were not previously [Ex. 73-90, p. 55].

In the case of formaldehyde, no squamous cell carcinomas of the nasal cavity were observed in the CIIT experiment in the control rats. Thus, when the multistage model is used to predict extra risk, it is not possible to assume that formaldehyde and carcinogens that cause the background incidence interact. Use of the experimental data in this manner does not reflect the fact that nasal carcinomas occur in rodents, albeit rarely. As Dr. Schneiderman pointed out at OSHA's hearings:

I think I indicated earlier that the multistage model makes the assumption that there are no new cancers in the universe. If there are no new cancers in the universe, there must be some background. If you do some dose-response curve fitting without using background, you've denied that assumption of the multistage model. So you're using the multistage model while denying a piece of the multistage model, and that seems to me to be illogical [Tr. May 7, 1986, p. 143].

How the failure to take the low background incidence of nasal cancer in rats into account affects the estimate of risk can be examined by assuming a plausible but arbitrary background rate to substitute into the multistage model. The incidence must be less than 1 cancer in 156 animals, which would have been detected in the CIIT study. Data from the National Toxicology Program, where only one to three sections of the nasal cavity were analyzed, indicated three occurrences of squamous cell carcinoma of the nasal

cavity in 4,794 F-344 rats [Ex. 69-15, p. 13]; this figure would most likely underestimate actual risk. Thus, an incidence of 1 in 1,000 seems to be a reasonable assumption for background incidence, and moreover, it is approximately the same order of magnitude of risk that humans experience from nasal cancer. Under these circumstances, using Global 82 and assuming a 5 stage model, the resulting coefficients are $q_0 = 0.87 \times 10^{-3}$, $q_1 = 0.25 \times 10^{-5}$, and $q_5 = 0.17 \times 10^{-5}$. At 1 ppm, the predicted extra risk per 100,000 workers is 0.42 (MLE) and 256 (UCL); at 2 ppm these figures are 9.5 (MLE) and 516 (UCL) per 100,000; at 3 ppm they are 62 (MLE) and 807 (UCL) per 100,000. As can be seen from this analysis, the influence of background rates in the region of interest to OSHA are minimal; there is no significant influence on the estimates of risk for either the MLE or the UCL. Consequently, OSHA concludes that the failure to take background rates into account has little influence on the ability of the CIIT rat data and the multistage model to derive a dose-response curve.

Species to Species Conversion: The quantitative assessment of human risk derived from experimental animal data is complicated by differences between species that potentially affect the degree of response to carcinogenic substances. According to the OSTP Report on Chemical Carcinogens [Ex. 73-90], these factors include differences between humans and experimental test animals with respect to life span, body size, genetic variability or population homogeneity, existence of concurrent disease, pharmacokinetic effects, and exposure regimen.

The traditional approach to species-to-species extrapolation has been to use some standardized baseline, or scaling factor. The OSTP report [Ex. 73-90] indicated that the best agreement between observed and predicted human cancer risk is often obtained when a body weight or body surface area correction is employed. However, the report cautioned that experience in this area is very limited and that the use of any standardized dosage scale for species scale-up is only a crude approximation. The choice of a particular dosage scale affects the magnitude of the projected risk.

The OSTP report cautioned that body weight/body surface area corrections may appear to fit carcinogenicity data in rats and mice because of experimental design limitations. To test for cancer, investigators generally determine the maximum tolerated dose (MTD) and administer the chemical at various

fractions of the MTD. The MTD, itself, probably depends on body weight/body surface area, which may be sufficient to account for apparent differences in carcinogenic potencies between species.

Of the various risk assessments on formaldehyde available in OSHA's record, only two [Exs. 70-1; 138-C] employ scaling factors. The Center for Policy Alternatives (CPA) estimated that 1 ppm of human exposure would be the equivalent of 0.5 ppm in rats (on a body weight basis), about 3.3 ppm of exposure in rats (on a body surface area basis), and about 9.5 ppm based on nasal cavity surface area. Based on comparison of tumor incidences between rats and mice in the CIIT study, CPA elected to use the intake/body surface extrapolation for "midrange" estimates of risk since 14.3 ppm in mice should yield the same incidence as 5.6 ppm in rats [Ex. 70-1, pp. 3-59 to 3-61].

The CPA rejected use of nasal cavity surface area corrections because differences in respiratory anatomy between humans and rodents make it likely that the nasal passages in humans do not define the total area likely to be exposed to formaldehyde. OSHA agrees with this conclusion, noting further the lack of quantitative data on nasal surface areas [Tr. February 1985, pp. 15, 80-82] and the potential uncertainties introduced when there is also exposure to dust particles that contain formaldehyde.

While CPA favored body surface area corrections because this scaling factor best explained the experimental relationship between rats and mice, relative differences between species might be explained by the mouse's ability to suppress its breathing rate when exposed to irritants [Ex. 70-24]. Either argument indicates that assessment of the mouse data on a strict ppm basis, without scaling factors, is fallacious and will lead to underestimation of human risk from exposure to formaldehyde.

In general, when extrapolating data derived from dietary intake or gavage, OSHA has included a scaling factor in its quantitative assessments of risk derived from animal data. When using the inhalation data in rats to establish water quality limits for formaldehyde, Crump [Ex. 138-C] also employed a scaling factor. Scaling factors in species-to-species extrapolations also appear appropriate when the experimental data in animals are from inhalation exposure if systemic tumors developed or metabolic conversion of the chemical to the ultimate carcinogen occurred. This is not the case for formaldehyde.

OSHA has used average exposure, in ppm, as a measure of dose of

formaldehyde. When body weights, about 70 kg for men and 250 g for rats, are taken into account along with ventilation rates of 0.02 liters/min for rats versus 20 liter/min for men, the amount of exposure to a worker exposed for 8 hrs/day, 5 days/wk, for 45 years in ppm is nearly identical to the exposure (in ppm) of the CIIT rats administered formaldehyde 6 hrs/day, 5 days/wk, for two years. This position was also taken in OSHA's proposal. While the decision to assess human risk on the basis of the CIIT rat data without use of a scaling factor is pragmatic, it has also been widely applied in other risk assessments for formaldehyde [Exs. 42-29; 42-31; 42-109; 69-15; 73-149]. Since the proposal was published, evidence has also grown to support the choice of average exposure as the measure of dose rather than cumulative exposure (*i.e.* ppm-yr) as the most appropriate measure of dose.

The decisions regarding scaling factors and average exposure as a measure of dose are unrelated to the extensive discussion OSHA received regarding administered versus delivered dose as a measure of risk. Arguments regarding the validity of pharmacokinetic models and alternative descriptions of dose were unrelated to species-to-species extrapolation scaling factors, and proponents of the pharmacokinetic model also used parts of formaldehyde inhaled per million parts of air, ppm, to describe dosage [Ex. 63].

Site Concordance: The assumption that permits investigators to extrapolate evidence of carcinogenicity in animals to predict human risks is that "on a biochemical and molecular level, there are important similarities among mammalian species" [Ex. 73-90, p. 11]. Most organic carcinogens require metabolic activation to exert their cancer-inducing properties [Ex. 73-90, p. 12]. There are enzymatic differences in metabolic activation between species, however, so that the precise anatomical site at which a tumor develops may differ between rodents and humans. Thus, in estimating human risk, OSHA generally does not presume that the risk predicted from animal data necessarily applies only for the specific tumor seen in animals.

Formaldehyde is unlike most organic carcinogens in that it appears to be a direct acting carcinogen, affecting the immediate site-of-contact. For this reason, a potential for much greater site concordance between animals and humans exists than usual. Even so, there are anatomical differences between the rodent and human respiratory system that must be taken into account. Rats

have elaborate nasal passages compared with humans, and their air chambers are substantially more effective than human noses in trapping inhaled materials. In contrast, the rat has a short bronchial tube, ending at the edge of the two lungs, one of which is multilobular. The human has a long bronchial tree, extending deeply into the lungs. In addition to these anatomical differences, humans, unlike rats, are not obligated to breathe through the nasal cavity. Consequently, experts in the area of comparative carcinogenesis expect that the entire human respiratory system is at risk of developing cancer from direct contact with formaldehyde [Exs. 90; 98; 100-A].

Epidemiologic studies indicate that certain workers exposed to formaldehyde and other chemicals have an excess of brain cancer. If brain cancer is related to formaldehyde exposure, it is likely that it occurs through metabolic activation, or through an even more indirect mechanism. The processes leading to brain cancer would be quite different from those leading to respiratory cancer. Because OSHA's assessment of human risk is based on assumptions that formaldehyde is direct acting and that there is a partial site concordance between species, the quantitative risk assessment does not take cancer at remote sites, such as brain cancer, into account.

Benign Tumors: Throughout OSHA's rulemaking on formaldehyde, opinion as to relevance of the benign tumors seen in the CIIT study to human cancer risk has been conflicting. Three consultants for the FI; Dr. Robert Seilken, a statistician; Dr. John Clary, a toxicologist; and Dr. Robert Squire, a pathologist, expressed opinions that the benign tumors should not be included in risk assessment [February 13-15, 1985; pp. 65-67, 72-73, 409-412].

The FI submitted that it was incorrect to combine polypoid adenomas with squamous cell carcinomas in quantitative risk assessment. The FI rejected the use of the polypoid adenoma data to predict cancer risk because: (1) There was no dose-response relationship (more adenomas were seen at 2 ppm than at 5.6 ppm); and (2) there was no evidence that the adenomas progressed to cancer. Furthermore, the inverted dose-response relationship could not be explained by early mortality or squamous metaplasia. According to the FI, OSHA's Cancer Policy expressly requires that the nature of the tumors be considered in assessing risk, and they further pointed out that polypoid adenomas are not frequent or life threatening in the workplace [Ex.

69-18], and therefore should not be used in assessing risk.

Although the FI questioned the relevance of the adenomas, the CIIT report [Ex. 12] clearly acknowledged that the polypoid adenomas were formaldehyde-related, as did Drs. Squire and Clary [Tr. Feb. 1985, pp. 65-67, 72-73]. The CIIT also indicated that nasal adenocarcinomas, seen in the 14.3 ppm rats, are malignant counterparts of the polypoid adenoma [Ex. 73-81E], indicating that, under certain circumstances, the adenomas may progress to cancer. The polypoid adenomas were incidental findings at the time of microscopic examination, however, and these lesions were not the cause of death of any animal [Ex. 73-81E].

At OSHA's public meeting on formaldehyde, the CIIT scientists postulated that the polypoid adenomas could be used in quantitative risk assessment if the likelihood of benign tumors becoming malignant could be determined. They examined the literature on human nasal tumors, on the human counterpart to the polypoid adenoma (the microcystic papillary adenoma), and also data from skin painting studies in animals to conclude that approximately one in 50 of the benign tumors might become malignant [Tr. February 14, 1985, pp. 246-253].

In an article published after the public meeting, however, Drs. Swenberg and Boreiko of the CIIT cautioned about the use of adenomas in risk assessment [Ex. 73-81E]. They stated:

The present state of knowledge on conversion rates of polypoid adenomas to adenocarcinomas is minimal to inadequate to derive a precise ratio for malignant transformation. Such a ratio is necessary if the polypoid adenomas are incorporated into a quantitative risk assessment for cancer, since these benign tumors were not life threatening and were clearly not cancer. At exposures of 6 ppm or less, no malignant transformation occurred. Thus, the ratio is less than 1:14 at exposures of occupational concern.

The Consensus Workshop on Formaldehyde's Risk Estimation Panel did not take a position as to whether benign tumors should be included in a quantitative risk assessment for formaldehyde, stating only that the benign tumor data should not be combined with the malignant tumors because they represented different tumor types [Ex. 70-56].

In a contrasting viewpoint, Dr. Roy Albert, OSHA's expert witness on experimental carcinogenesis and the head of EPA's Carcinogen Assessment Group, felt that the adenomas should be taken into account in quantitative risk

assessment. Dr. Albert pointed out that benign tumors are deleterious health effects in themselves and that combined exposure to formaldehyde and other air contaminants, for example, cigarette smoke, might transform the adenomas to a malignant tumor [Tr. May 5, 1986, p. 164]. Dr. Albert felt that the arguments to reject the adenoma data because of the lack of a dose-response relationship were unconvincing. Dr. Albert pointed out that squamous metaplasia occurred at high doses because of formaldehyde's irritating effects. On the other hand, at lower doses, there was insufficient irritation to produce much squamous metaplasia. Thus, Dr. Albert felt that the carcinogenic action of formaldehyde could very well account for the presence of adenomatous lesions at low doses instead of squamous lesions [Tr. May 5, 1986, pp. 166-167].

To address the major concerns expressed about extra risk contributed by the polypoid adenomas, OSHA assessed how inclusion of malignant forms would affect low-dose predictions using the 5-stage multistage model. As the CIIT investigators indicated, the conversion rate for cancers from polypoid adenomas cannot exceed approximately 1 in 20. This results in a total nasal-tumor bearing animal incidence rate of 1 in 3,120 as a background rate ($\frac{1}{156} \times \frac{1}{20}$), 8 in 3,180 at 2 ppm, 2.3 in 155 at 5.6 ppm, and 97 in 141 at 14.3 ppm. Fitting these adjusted figures with the 5-stage multistage model yielded a curve with coefficients of $q_0 = 3.2 \times 10^{-4}$, $q_1 = 9.2 \times 10^{-4}$, and $q_5 = 1.9 \times 10^{-6}$. As anticipated, this dose-response curve predicted a higher incidence of cancer at low doses than the 5-stage model derived from the carcinoma data alone. Because of the large contribution from the adenomas at 2 ppm, this analysis resulted in MLEs of 46, 92, 189, and 320 cancers per 100,000 at 0.5, 1, 2, and 3 ppm, respectively. These figures are 3.7 to 1,170 times greater than the corresponding MLEs derived from the squamous cell carcinoma. (UCLs cannot be calculated because of limitations imposed by the computer program.) As described in the ORA Report [Ex. 43], even with some correction for potential malignancy, the adenomas totally dominate the low-dose estimates, virtually discounting a contribution from the malignant squamous cell carcinomas.

OSHA has not used this adjusted model in its final assessment of risk because the polypoid adenomas were produced in only one study and because there does not appear to be any biological justification for combining data representing tumors of two distinct cell types. This adjustment, however,

implies that the MLE of risk calculated exclusively from squamous cell carcinoma data might seriously underpredict low-dose risk.

OSHA's approach regarding the polypoid adenomas and the squamous cell carcinomas is consistent with that taken by the OSTP with regard to combination of tumors of different types. According to the OSTP Report [Ex. 73-90, p. 54] the grouping of lesions for evaluation should be based on commonality of histogenic origin. Therefore, adenomas should not be combined with carcinomas for the purpose of establishing a value for the incidence of cancer at a specific organ site. The OSTP report also indicates that "life shortening tumors should not be combined with non-life shortening tumors" [p. 54]. As noted earlier, the carcinomas were life shortening; the adenomas were not.

The Consensus Workshop's Risk Estimation Panel took no position on whether or not a separate analysis of risk based on the adenoma data should be conducted. OSHA found no evidence that the adenomas present a risk of death (although these benign tumors would represent a material impairment of health). OSHA also recognizes that great uncertainty is associated with any attempts at quantification of risk based on the benign tumors. Since this regulation is justified on the basis of a significant risk of material impairment of health and functional capacity without relying on the benign tumor data, OSHA has not used assessments of benign tumors to quantify human risk. OSHA's quantitative assessment of risk for formaldehyde is based solely on the malignant tumors.

The OSHA decision to base the quantitative risk assessment on squamous cell carcinoma data is consistent with the approach taken by the Consensus Workshop on Formaldehyde [Ex. 70-56], and does not make use of models, such as that of Kang and Chu [Ex. 73-115], which are based on total nasal tumor-bearing animals whether the animals had adenomas or carcinomas.

The Origins of OSHA's Risk Assessment for Formaldehyde: Early assessments of risk of formaldehyde exposure that were conducted by or for OSHA employed the 3-stage multistage model to define a dose-response curve based on the CIIT rat data. As new options became available, OSHA also explored alternatives using the 5-stage model. This evolutionary process was also being undertaken by other investigators.

For example, Dr. Kenneth Brown described a number of models for fitting the CIIT rat data, corrected for early sacrifice by estimating the fractions of a lifetime that the rats were at risk. Using this approach, for the multistage model, he predicted a risk of 43.4/100,000 (MLE) for lifetime exposure at 3 ppm with a corresponding UCL of 633/100,000. Using another approach, in which only the animals examined at 24 months were evaluated, he developed a prediction of 263 deaths/100,000 for the MLE with a corresponding UCL of 1,819/100,000 at 3 ppm based on the multistage model [Ex. 69-15]. Using a similar approach to Dr. Brown's for calculation of rats-at-risk, EPA predicted an MLE of 60/100,000 with a UCL of 600/100,000 [Ex. 73-149].

In comments to HUD on a manufactured housing product standard [Ex. 42-31], the CPSC described a new methodology to estimate excess risk of cancer associated with formaldehyde exposure. To define the dose-response curve, CPSC used data from the CIIT rat study. Although they examined other data, including the NYU rat study and the CIIT mouse data, the other information was considered inappropriate for inclusion in the quantitative assessment for various reasons. The mouse data were rejected because of the smaller number of mice at risk due to unrelated early deaths and the decrease in respiration rate that the mice experienced. The NYU study was not used because it was performed at a single dose, so that the information was inadequate to define the shape of the dose response curve.

The multistage model was used to calculate individual risk at low doses. Two separate equations were used to describe the entire dose-response curve; one equation represented doses below 1 ppm; the other, exposures over 1 ppm. Level of exposure for continuous exposure (L) was considered to be 0.13 times the average dose in ppm administered to the CIIT rats. At levels above 1 ppm, the lowest lifetime estimated excess risk was predicted from the equation, $0.000037L^4 + 0.000011L^5$. At levels below 1 ppm, the maximum lifetime estimated risk was calculated from the linear relation, $0.028L$. This risk estimate below 1 ppm presumed interactions with background processes. Based on these equations, the CPSC calculated the MLE of risk as 48 per 100,000 with an UCL of 2,800 per 100,000 for continuous lifetime exposure at 1.0 ppm.

OSHA's assessment given in the ORA Report [Ex. 43] was derived from modifications made by OSHA's Office of Risk Assessment to the CPSC

analysis. The number of rats-at-risk was calculated by eliminating animals killed before 24 months, those whose nasal cavities were not histopathologically examined, and all animals dying before the first cancer was observed at 11 months. The mathematical model chosen in the ORA report was the multistage model not restricted by the number of experimental doses. Under this circumstance, the dose-response curve based on squamous cell carcinomas in the CIIT rats best fit a 5-stage model with positive coefficients for the MLE in only the fourth and fifth terms. This multistage model gave a better fit to the experimental data than the three-stage model [Exs. 42-29, 42-109; 94] which is also a plausible model. Predictions of lifetime risk using the ORA multistage model with two positive parameters for the MLE, $q_4 = 3.954 \times 10^{-4}$ and $q_5 = 1.597 \times 10^{-4}$ [Ex. 43; 50 FR 50460], are presented in the table below.

OSHA's conclusions regarding the number of rats at risk, the appropriateness of the CIIT rat study to predict human risk, the species-to-species scaling factor to apply, and the multistage model as the single most reliable estimate of dose-response remain unchanged since the calculations were performed for the ORA report [Ex. 43]. Indeed, these were not controversial issues in the rulemaking, and there was substantial agreement in the record on these points. The figures, shown in Table 3, which were derived from the analysis of the CIIT rat data and the 5-stage multistage model conducted in the ORA Report [Ex. 43], remain relevant for OSHA's final assessment of extra risk from exposure to formaldehyde.

TABLE 3.—LIFETIME RISK OF CANCER PER 100,000 WORKERS

Exposure level (ppm)	MLE	UCL
3.....	71	834
2.....	11.4	534
1.....	0.6	264
0.5.....	0.03	132
0.1.....	0.001	26

The Updated CPSC Model: In written comments supplied with their testimony given at the OSHA hearings, the CPSC submitted their most recent risk assessment based on the CIIT rat data [Ex. 86-26]. Corrections for sacrifices and early deaths were identical to those performed in the ORA report, leading to the same fit as the ORA report to the five-stage model. However, the CPSC made different assumptions regarding calculations of risk based on the 5-stage

model. All data are reduced to unit estimates of risk. Equations for these unit estimates are:

Lifetime Estimated Excess Risk

$$(MLE) = 0.15 \times L$$

Lifetime Estimated Excess Risk

$$(UCL) = 0.29 \times L$$

where L is the level of exposure administered for a lifetime. For example, according to the CPSC calculations, if a person is occupationally exposed to 3 ppm of formaldehyde 8 hrs/day, 5 days/wk, for 20 years, the upper and lower estimates of risk would be calculated as risk = unit estimate $\times 8/24 \times 5/7 \times 20/70$ assuming a lifetime of 70 years. By this equation, the upper and lower estimates of risk are 5,600 and 390 per million (p. E-30).

Dr. Cohn, of CPSC, compared the Blair *et al.* data with risk estimates based on the equations for unit estimates of risk, shown above. In the epidemiologic study, 268 respiratory system cancers were observed in white males with 248 expected, an excess of 20 cancers. The excess of cancers expected based on UCL calculations from the CIIT rat data was 8.7, less than found in the human study [Ex. 114].

This analysis performed by CPSC illustrated how the limited data from humans can be used to determine whether or not risk estimation models based on animal data yield plausible predictions. Because the human evidence has not clearly demonstrated a dose-response relation, because of uncertainties in exposure estimates, and because other carcinogenic agents present in the workplace could have contributed to the observed risk, OSHA still places greater weight on dose-response estimates derived from the CIIT rat data.

Use of Epidemiologic Data to Predict Risk: The OSTP Report [Ex. 73-90] indicated that even though epidemiologic studies are free of problems with species-to-species extrapolation, when epidemiologic data are used in risk estimation, the available data to complete a thorough study are often not available. According to the report (pp. 82-83):

The marked variability in human sensitivity must be taken into account. Furthermore, there are a number of other problems that may be encountered with attempting to use epidemiological data to construct estimates of lifetime risk for a subset of the general population. . . . Epidemiological investigations are often conducted for only a limited period of time, and failure to adjust properly for incomplete followup of subjects can significantly affect the estimation of lifetime risk. Similarly, estimation of lifetime cancer risks is also

complicated if the available epidemiological data involve exposures that fall far short of a normal lifespan. For example, if a multistage mechanism is assumed, then the effect of early termination of exposure will be dependent on the stages of the carcinogenic process that are influenced by the exposure.

And, as stated by Dr. Schneiderman [Ex. 96]:

In general epidemiology is not an ideal tool for developing exposure-response relationships, and is even poorer in developing dose-response relationships. Humans are exposed to many materials, making it very hard to ascribe a given response to a single, specific cause. The exposures are often erratic, sporadic and of unequal duration and intensity * * *. In general, before epidemiologic results become convincing, there needs to be some replication, or evidence of some other internal, logical consistencies. How much replication or what internal logical consistencies are often matters of taste, rather than objectively determined (p. 3).

In the proposal, OSHA indicated the difficulties in detecting risks of a magnitude of 7 per thousand in an epidemiological study. When adult white males have a 7 percent probability of death from lung cancer [50 FR 50446], one of the suspected sites of action in humans:

The relative risk or SMR from a study of workers exposed to 3 ppm should be approximately 1.10 (7.7%/7.0%). Such a relative risk most likely would not achieve a level of statistical significance, even in a large study. In this context, it is again noteworthy that the study of Acheson *et al.* demonstrated a significant excess of lung cancer (SMR=124) among the cohort of workers where the largest majority experienced "high" levels of formaldehyde (greater than 2 ppm), but that an excess of lung cancer was not observed at five additional facilities, where the majority were exposed to "low" or "nil" levels (less than 0.1 to 0.5 ppm).

Since publication of the proposal, the Blair *et al.* study has become available. This study [Ex. 156-A4] reported an SMR of 112 for cancer of the respiratory system in white male workers ever exposed to formaldehyde. This information is relevant for estimating extra risk in a "typical worker" population, most of whom are still alive.

The OSH Act, however, requires that the health and safety of workers be assured at all times, even if a worker is exposed for an entire working life of 45 years. A subgroup in the Blair *et al.* study, workers first exposed at least 20 years before the study cut-off date provides estimates most relevant to the risk associated with exposure to formaldehyde for up to a working life. Those having any exposure to formaldehyde (less than 0.5 ppm-yr to greater than 5.5 ppm-yr) had a

statistically significant increase of lung cancer of 132.

OSHA has already indicated a preference for average exposure rather than cumulative dose to assess the risk of exposure to formaldehyde. Although Blair *et al.* did not report their results in terms of average exposure, a regression analysis of the data provided by Sterling and Weinkam [Ex. 200-1] looked at the data for the "typical workers" in this manner. Persons whose exposure averaged 1.15 ppm had a 36 percent greater chance of dying of lung cancer than those who were exposed at 0.18 ppm. This information is relevant as a measure of relative risk of cancer to exposure from formaldehyde. By use of a proportionate relationship, OSHA could determine that at 1 ppm, an SMR of about 130 would be expected; at 2 ppm an SMR of about 160 would be expected. For white males, the annual rate for lung cancer is 64/100,000 (1970-1979 data). A 30 percent excess risk over 45 years would mean that 864 cases per 100,000 workers would occur from their exposure to formaldehyde.

Sterling and Weinkam evaluated the risk of buccal cavity and pharyngeal cancer in white male hourly resin plant workers. Persons whose average exposure was greater than 0.5 ppm (*i.e.* 1.15 ppm) had a relative risk of 2.3 for these cancers compared with workers exposed to average concentrations less than 0.5 ppm (average 0.18 ppm). Thus, the approximate SMR for no exposure is 70, at 1 ppm it is 230, and at 2 ppm it is 390.

This information can be used to compare risk of pharyngeal cancer with predictions from animal data. Annual rates for nasopharyngeal cancer are 0.4 per 100,000 in white males (1970-1979 rates). At 1 ppm, this would mean that at least 22 cases of nasopharyngeal cancer per 100,000 workers exposed to formaldehyde would develop as the result of their workplace exposure.

Several other studies have information regarding current exposures and epidemiologic data from workers first exposed a number of years earlier. This information can be used to determine an upper bound of risk.

NIOSH undertook extensive surveillance of three apparel manufacturers in support of the Stayner *et al.* study. Average exposures were 0.15 ppm for all three plants combined (range of geometric means 0.14-0.17 ppm). Cancer of the buccal cavity was elevated, with an SMR of 343.

Vaughan *et al.* [Ex. 202] reported a risk ratio of 3.8 for developing cancer of the nasal cavity and sinuses in resin and glue workers. OSHA estimates that these workers probably had exposures

in the past of at least 1 ppm even though recent exposures seem to be lower.

Vaughan *et al.* also reported an odds ratio of 5.5 for nasopharyngeal cancer for persons who had resided in a mobile home for 10 or more years. Although no exposure estimates are available from the study, some order-of-magnitude information can be derived.

Formaldehyde exposure in mobile homes is thought to be greatest when the home is new, decreasing with time, with offgassing complete in about 10 years. For exposures beginning in the range of 0.4 to 1 ppm, average exposure in the 10 year period would be in the general range of about 0.2 ppm for up to a 168-hour week, which would correspond roughly to an occupational exposure over a 40 hour week of 1.2 ppm. However, there are known dose-rate effects of formaldehyde not taken into account by this method of estimating exposure, so that risk to the worker in such circumstances might be greater.

All three of these studies yield risk estimates greater than that projected from Sterling and Weinkam's analysis of nasopharyngeal cancer in Blair *et al.*, but they are well below the estimates derived from the lung cancer data.

Uncertainties in the Extrapolation of Risk: In experimental bioassays of formaldehyde, the animals were exposed to formaldehyde gas generated from paraformaldehyde. While some humans are exposed under similar conditions, most are not. Many are exposed when they handle formalin solutions, which will lead to a different exposure pattern that might not lead to results identical to those obtained for exposure to pure formaldehyde gas. To the extent that the skin is not intact, formaldehyde may become systemically absorbed, leading to both a greater exposure potential than predicted by measuring airborne exposure alone and a different distribution of the carcinogen inside the body. There is no information available that is sufficient for OSHA to be able to predict whether such dermal exposure will enhance the risk from formaldehyde. OSHA's conclusions regarding cancer from dermal exposure are based on the nonpositive results seen in animals with intact skin and the presumption that workers wearing protective clothing will be adequately protected to prevent any risk from skin contact.

The major use of formaldehyde is in the production of resins. These resins are capable of offgassing formaldehyde. They may also make a substantial contribution to the overall amount of formaldehyde exposure because of

formaldehyde's entrainment on materials such as lint (from permanent-press material) or wood dust from sawing materials such as hardwood plywood or particleboard [Tr. Feb. 15, 1985, pp. 594-598]. Depending on the size of the inhaled particle, how easily formaldehyde is released to surrounding tissue when formaldehyde bearing particles are inhaled, and the relative contribution of the particle-borne formaldehyde to the total dose inhaled, substantially more formaldehyde may penetrate into the airways and even into the lung than would occur if exposure were solely to formaldehyde gas, leading to an overestimation of risk from human data where combined exposures occurred but exposure was assessed solely by estimating the gaseous component.

The Blair *et al.* study shows that nasopharyngeal cancer excesses occurred in persons exposed to both formaldehyde and particles. They also found an excess lung cancer risk in industrial worker populations exposed to formaldehyde. OSHA has concluded that the excesses of cancers seen at these sites were probably caused by exposure to formaldehyde (see section on Cancer Epidemiology). This suggests that the form in which exposure occurs may influence the response and contribute to the uncertainty in extrapolating human risk from exposures of isolated experimental animals.

Workers, who do not live in isolated environments, may be more likely than animals to develop cancers because of additive or multiplicative effects of formaldehyde exposure combined with exposure to other carcinogens. Smoking would be of concern, since smoking should affect mucociliary flow, possibly disrupting one mechanism that helps protect against formaldehyde carcinogenesis. Numerous other carcinogens are present in the environment. For example, persons who are also exposed to wood dust appear to be at much greater risk of developing nasal cancer than if they were exposed to either formaldehyde or wood dust alone (see epidemiology section). These factors would tend to make estimates of risk based on human data higher than estimates based on laboratory animals.

It has been argued that because formaldehyde is a normal constituent of the mammalian organism, there should be a practical threshold or tolerable level of exposure [Ex. 73-15]. If there is a true threshold for formaldehyde's effects, it must lie below the 1 to 2 ppm range of exposure where substantial evidence of formaldehyde's ability to

react with tissue at target sites exists in both humans and animals (see health effects).

The available information also indicates that there is a nonlinearity at low doses, probably because of protective mechanisms such as reaction with the respiratory mucous. The dose-response curve predicted from the CIIT rat data and the multistage model does not reflect any low dose nonlinearity, which means that the risk of cancer at very low doses might be less than predicted.

For reasons stated in the section reviewing epidemiologic studies, it is not possible to conclusively determine that formaldehyde has not caused distant-site tumors in some workers. On the other hand, the failure to find distant-site tumors in the CIIT animals, which received high exposures of 14.3 ppm for up to 2 years, suggest there is no such effect. OSHA's risk assessment does not take distant-site cancers into account. This might lead to an underprediction of risk if distant-site tumors are related to formaldehyde exposure.

Inbred rats cannot be equated exactly to the heterogeneous human population. Tolerance distributions for humans should be greater than in an inbred strain of rats. Thus, a greater number of persons will react at a lower dose than rats (and conversely, a number will react only at doses higher than the animals).

In the formaldehyde hearings, Dr. Mirer of the UAW asked Dr. Schneiderman to comment on how the steepness of the dose-response curve would be affected because of genetic similarity of laboratory rats as compared to much more genetically diverse humans [Tr. May 7, 1986, pp. 98-99]. Dr. Schneiderman replied that there is every indication that dose-response relationships in humans are flatter than for experimental animals since humans are genetically diverse and that there are also likely to be very highly sensitive individuals [Tr. May 7, 1986, pp. 99-100]. The greater genetic heterogeneity found in humans than in in-bred rats would affect low-dose risk prediction for humans, Dr. Schneiderman commented; if humans, on the average, are exactly as sensitive as the experimental animals, a substantially greater response at low doses will occur in humans than in animals [Tr. May 7, 1986, pp. 100-101]. This would also mean that the effects of lowering the PEL on reducing cancer risk might be less than predicted based on animal data.

While human data might appear, on the surface, to be more able to

accurately predict human cancer risk, this is so only if a high degree of confidence can be placed in the data. The small increase over background rates for lung cancer, the rarity of nasal and nasopharyngeal cancer, and the very serious questions raised at OSHA's hearings regarding the validity of the Blair *et al.* exposure data leave great uncertainties regarding the ability of the available human data to accurately predict risk.

There are also problems in extrapolation of the rat data to the human situation in the workplace. Humans exposed at concentrations of 1 ppm and below may be poorly represented by animals exposed at 14.3 ppm, the only dose in animals where the cancer incidence was statistically significant and the dose that contributes most strongly to the highly nonlinear dose-response curve. At this concentration, which approaches the maximum tolerated dose (MTD), increased availability of single-stranded DNA and enhanced cell turnover make it more likely that a mutation will become fixed. Decreased mucous flow and ciliastasis probably also enhance the carcinogenic effect.

It is likely that the dose-response curve derived from experimental data represents a series of reactions, or mechanisms of action, and that a different reaction predominates at low doses as compared to the MTD. Because the data at 14.3 ppm represent the only statistically significant finding, great weight is given to this point in defining the dose-response curve. As seen for Brown's conditional model [Ex. 42-22], if this point estimate is too high, low dose predictions will be too low.

Unlike the laboratory rat, humans do not live in an isolated environment. There are many competing risks, for example, from heart disease or automobile accidents, which may remove humans from the possibility of contracting cancer from formaldehyde exposure at some later date. Conversely, humans are exposed to cigarette smoke and other industrial and environmental carcinogens which add to or enhance the risks of respiratory cancer. The overall influence of such competing risks is unknown.

OSHA's Estimation of Risk of Cancer

In the proposal, OSHA described a number of quantitative risk assessments for formaldehyde [Exs. 42-29; 42-31; 42-109; 43; 45-1; 63; 69-15; 70-1; 73-115; 73-149] (see 50 FR 50447-50461).³ Since

³ After OSHA's record on formaldehyde was closed, EPA released a new risk assessment on

then, two more assessments have become available to OSHA, a revised version of the CPSC assessment [Ex. 42-31] which includes updated information [Exs. 86-10; 114] and an assessment conducted for the purpose of establishing water quality criteria [Ex. 138-C].

While it is possible that other types of assessments may be reasonable, OSHA has relied only on those that used the multistage model and the CIIT rat data, corrected in some manner for serial sacrifice of the animals. The multistage model is clearly superior to the other mathematical descriptions of risk because it is founded on theories of carcinogenesis compatible with available data on formaldehyde. The quality of the CIIT rat study is not in doubt. OSHA has great confidence that these two restrictions ensure that only plausible estimates will be considered.

In contrast, OSHA finds that information regarding use of the MLE versus the UCL did not provide a compelling argument in support of either position; there are merits to both approaches. The UCL cannot stand alone from the MLE; the MLE is the basis for the UCL. Thus, the UCL can never be a point estimate of risk. However, for substances other than formaldehyde, it has been highly unusual to find human data available that gives so much greater risk estimates than some of the estimates based on reasonable interpretations of the animal data. Thus, for formaldehyde, OSHA believes that use of the UCL to provide an estimate of the possible range of risk faced by humans has merit. In contrast to the position taken in the proposal when much less human data were available, OSHA has not rejected risk estimates based on the UCL.

Six estimates fitting the above criteria and reporting either the MLE, the UCL, or both estimates were available in the formaldehyde record [Exs. 42-29; 43; 69-15; 73-149; 86-20; 114] (these were presented in either the proposal or in the previous discussion); at 3 ppm the extra risk associated with exposure to formaldehyde for a working lifetime (approximately 45 years) ranged from 43.4 [Ex. 69-15] to 620 [Ex. 42-29] per 100,000 for estimates based on the MLE with UCLs ranging from 600 [Ex. 73-149] to 1,819 [Ex. 69-15] cases of cancer per 100,000 workers. While this appears to be a wide range, it is substantially less than that first confronting OSHA when

the Agency began its assessment of the need for a revised regulation [Ex. 61]. OSHA cannot resolve the information with any greater degree of precision because of the steepness of the dose-response curve near the region of interest and because of discrepancies in both the shape of the curve and magnitude of the risk between the human and animal data. There are considerable uncertainties, as described above, which may influence the "true" risk of exposure to formaldehyde. Improvements in defining the dose response curve would require resolution of these uncertainties. A much larger animal bioassay with additional exposure groups in the region of interest would be useful, but this is probably impractical as a research project. Improvements in the human data would require much more accurate information on historical exposure of each worker and a cohort whose exposures to formaldehyde occurred at levels much greater than those of existing studies, *i.e.* Acheson, Blair, Vaughan, Stayner, and their coinvestigators. Such a data base does not appear to exist.

OSHA's estimates of extra risk to workers exposed at 1 ppm for a working life are based primarily on assessments performed by Clement Associates [Ex. 42-29] for OSHA and in the ORA Report [Ex. 43]. The range of risks predicted by use of the MLE and UCL estimates from these models is 0.56 to 264 cases per 100,000 workers. This corresponds to a decrease in risk of 6 to 471-fold for a worker whose exposure is decreased from an average of 3 ppm to 1 ppm.

When only the evidence in experimental animals is considered, predictions of risk in the lower end of the range appear to be more plausible estimates of risk. When existing evidence in humans is examined, both for nasopharyngeal cancer and for lung cancer, risk appears to be higher than risks suggested by the animal studies alone. This is why OSHA has chosen to include the UCL in estimating risk. Since considerable uncertainties exist in the low dose estimates, the real risk may be lower than that projected by any of OSHA's estimates. The additional uncertainties introduced by extrapolating the data across species must be considered, and the lower bound is recognized to be as low as zero.

OSHA notes that the predicted excess lifetime cancer risk estimates using an upper bound of the 5-stage model based on the rat carcinoma data are about equivalent to the excess cancer incidence observed in the epidemiological studies. As described

before, however, less weight must be given to the human data because of the great uncertainties involved in the exposure estimates, the possibility of substantial unreported exposure to formaldehyde through inhalation of particles bearing formaldehyde, exposure to peak concentrations, and the uncertainties inherently present in epidemiological studies where observed SMRs are only slightly elevated. Nevertheless, a UCL is not a point estimate of risk; this figure is represented by the MLE. The UCL is simply an upper bound derived from statistical considerations to give a limit that is very unlikely to understate risk, and, in general, may overstate actual risk. OSHA's use of the UCL in this case is supported by the human data. Thus, the estimates at the low end of the range based on the MLE cannot be rejected; they are at least as reasonable as those at the high end of the range.

Biological evidence indicates that the effects of formaldehyde are more strongly related to the concentration of formaldehyde than they are to duration of exposure. The CIIT study demonstrates the importance of concentration because the highest dose, 14.3 ppm, caused a much greater response than at 5.6 or 2 ppm. In the CIIT bioassay, animals were exposed to fairly uniform concentrations throughout the study; many workers are exposed to varying concentrations including excursions and peaks throughout the day. OSHA's estimates of risk based on the animal data, therefore, probably underestimate the risk of employees who have peak exposures. Excursions above the TWA level should result in substantially greater risk than predicted by averaging these concentrations with periods of low exposure to calculate a TWA. This might account for the greater risk seen in humans than what is predicted from the animal data since the Blair *et al.* study indicated that some of the workers received peak exposures.

Existing evidence is insufficient to quantify the extra risk that may be associated with peak exposure. OSHA does not believe that the risk of exposure for short periods throughout the workday, for example to 1 ppm for 30 minutes, is as great as the same exposure received throughout the entire workday, for example 1 ppm for 8 hours. Information available is not adequate to further quantitate risk for short-term exposures.

The old standard permitted ceiling exposures of up to 10 ppm; the revised standard will limit such excursions to 2 ppm. The new STEL requirement and other provisions of the revised standard

formaldehyde to the public. Although the revised assessment contains more data, assumptions used to define the dose-response curve are the same as the information contained in the EPA risk assessment cited in this document [Ex. 73-149].

should also provide protection to employees to reduce cancer risk. These provisions will work to further lower human risk and bring risk estimates closer in line with the MLE projections based on animal data.

Some employees are exposed to formaldehyde and to other carcinogens where the risk of such combined exposure is synergistic, and not merely additive. In such circumstances, lowering formaldehyde exposure will cause the risk of the combined exposure to decrease much more than would be predicted from the multistage model using data from experimental animals. This should also act to achieve a greater reduction in risk than can be quantitatively predicted.

To the extent that humans have protective mechanisms that will help to remove the formaldehyde inhaled before it can react with cells at the target site, exposure to low doses of formaldehyde may be less risky than extrapolation procedures can take into account. Again, this would imply that the standard may be more protective than it is possible to estimate from quantitative models.

As a consequence, OSHA believes that the entire standard for formaldehyde with a 1 ppm TWA and a 2 ppm STEL and industrial hygiene and medical provisions will likely decrease the risk of exposure to levels more representative of the lower end of the range of risks, and possibly to even lower values. Under such circumstances, OSHA believes that residual risk can be considered "insignificant".

Estimation of Risk of Sensory Irritation

In addition to the risk of cancer associated with exposure to formaldehyde, there is also a risk from the acute irritant effects of formaldehyde. Although other groups, including the Consensus Workshop [Ex. 50-56] and the EPA, have concluded that the data are insufficient to perform a quantitative assessment of the risk of sensory irritation from formaldehyde, OSHA has found it useful to conduct some type of analysis of risk even though it is not mathematically rigorous.

As discussed in the proposal [50 FR 50460-50461], OSHA's assessment is based primarily on two sources of data, a study of volunteer subjects by Anderson and Molhave [Ex. 42-10] and data collected in the Booz-Allen study [Ex. 8] conducted for SOCMA (now the Formaldehyde Institute).

Anderson and Molhave developed a scale of discomfort ratings. A score of 100 meant intolerable discomfort, a score of 83 implied strong discomfort, 50 implied discomfort, 17 implied mild to

slight discomfort, and 0 meant no effects. Following 5-hour exposures, healthy volunteers developed conjunctival irritation and dryness of the nose and throat at the following rates: in 19 percent exposed at 0.25 ppm, in 31 percent exposed at 0.42 ppm, and in 94 percent exposed at 0.83 and 1.6 ppm. Average subjective discomfort scores were 7 at 0.33 ppm (average of scores at 0.25 and 0.42 ppm); 11 at 0.83; and 18 at 1.6 ppm out of a possible total of 100.

In a study of formaldehyde exposure in 17 industries, SOCMA collected information on nose and eye irritation and calculated average exposure levels [Ex. 8]. Resin and plastics industries participating in the study indicated employees experienced no effect at average exposures of 0.3 ppm for 80 percent of the time, slight discomfort at exposures of 0.8 ppm for 12.4 percent of the time, discomfort at 1.8 ppm for 5.8 percent of the time, strong discomfort at 2.5 ppm for 0.7 percent of the time, and intolerable odor at 3.7 ppm for 0.3 percent of the time. Similar, although less complete figures were reported in several other industries (see Ex. 43, Table A p. 156). These figures are consistent with Anderson and Molhave's report where 81 percent of the volunteers exposed at 0.25 ppm and 69 percent of those exposed at 0.42 ppm experience no discomfort. Likewise, at higher levels of exposure, discomfort in the SOCMA study approximately corresponded to an average subjective irritant score of 50, strong discomfort to 83, and intolerable odor to 100 [Ex. 43].

Based on these two studies, the ORA report [Ex. 43] provided a rough evaluation of irritant effects that should be experienced at various levels of exposure. It was estimated that exposures over 3 ppm would be nearly intolerable to all workers, and between 1 and 3 ppm all workers would experience some discomfort to strong discomfort. For exposures between 0.5 and 1 ppm, 31 to 94 percent were expected to experience slight discomfort. At levels of 0 to 0.5 ppm, up to 20 percent would still experience slight discomfort.

These estimates were derived from responses of volunteer subjects and from recollections of workers. Hence, as a measure of irritation, they are limited to the qualitative descriptors assigned each level by the interviewees. The volunteer studies are subject to all of the problems concerning the representativeness of volunteers (often students) who are exposed for short periods as comparison groups for the usually older worker who may be exposed for many years. The worker

study has even more severe limitations because of the limited exposure data available and the potential for recall bias. Nevertheless, these irritant scores are remarkably similar to estimates derived by the National Academy of Sciences in 1981 [Ex. 42-87]. The NAS estimates are given in the table below.

TABLE 4.—PREDICTED IRRITATION RESPONSES OF HUMANS EXPOSED TO AIRBORNE FORMALDEHYDE

Concentration (ppm)	Percent of population giving indicated response	Degree of irritation
1.5-3.0	10-20	7-10
	30	5-7
0.5-1.5	10-20	5-7
	30	3-5
0.25-0.5	20	3
Less than 0.25	20	1-3

Irritation Index: 10=strong irritation, great discomfort; 7=moderate irritation, discomfort; 5=mild irritation, mild discomfort; 1=minimal irritation, minimal discomfort; 0=no effects.

The cumulative experience of workers and volunteers suggests that at concentrations below 0.5 ppm, the 20 percent response is one of simple odor detection with about half of these same individuals showing more severe, but transient effects of slight eye irritation and dry throat. At 1 ppm, nearly all persons who have not become acclimated to formaldehyde would be aware of its odor when first entering the worksite. Mild irritation of the eyes, nose, and throat would probably occur in about half these persons (50%); only half of these would complain of mild irritation (25%). At concentrations of 1.5 to 3 ppm, an increasing percentage of workers would develop eye, nose, and throat irritation even among those who have long-term exposure. These effects would be described as mild to moderate at lower levels, increasing to moderate to severe by 3 ppm. Concentrations of 3 ppm become uncomfortable to many workers, about 80 percent, and nearly intolerable to some, about 20 percent. Over 3 ppm, formaldehyde is intolerable to most persons.

Pharmacokinetic Modeling

Hoel *et al.* [Ex. 69-23-B4] developed a risk assessment model that assumes all nonlinearities observed in the dose-response curve are attributable to kinetic processes involved in the formation of carcinogen-DNA adduct. In this model, tumor response (p) is assumed to be a function of "effective" dose which, in turn, is some function of

administered dose. Calculation of "effective" dose, which is the concentration of carcinogen-DNA adduct at the target site, is based strictly on pharmacokinetic parameters. Even though the pharmacokinetic model may be simple or complex, the authors assumed that tumor response is a simple function of effective dose, *i.e.* the percentage of animals with tumors is linearly related to effective dose.

In the simplest case, formation of carcinogen-DNA adduct follows first order kinetics (*i.e.* rate of change over time is a constant). In this case, administered dose and effective dose are proportional, and the risk estimate is based on a 1-hit or single stage model.

To describe more complex interactions, Hoel *et al.* used a kinetic model of Gehring and Blau which takes activation, detoxification, DNA binding, and DNA repair into account. In this model, saturation of a detoxification pathway or DNA repair will lead to a nonlinear change in risk of developing cancer. Adjustment of the various rate constants also affects relations predicted between administered and effective dose, and hence low dose risk. A linear relationship represents first-order kinetics, a convex dose-response curve represents saturation of the activation system, a "hockey stick" curve represents saturation of detoxification or repair systems, and an "S-shaped" curve represents saturation of activation as well as saturation of detoxification or repair.

Starr and Buck [Ex. 63] applied the information on covalent binding of formaldehyde to the model developed by Hoel *et al.* [Ex. 69-23-B4]. At 6, 10, and 15 ppm the relative concentration of covalently bound formaldehyde was constant, 0.04 nmol/mg DNA/ppm. At 2 ppm, this value dropped to 0.011, and at 0.3 ppm, covalently bound formaldehyde could not be measured. For doses below 2 ppm, the authors presumed a linear relationship ($D=0.011 \times A$) between delivered dose (D) and administered dose (A).

Using the DNA binding data as a measure of delivered dose [Ex. 62] and tumor data through the first 24 months of the CIIT study [Exs. 12: 42-131], Starr and Buck estimated low-dose risk of exposure to formaldehyde using the probit, logit, Weibull, and multistage models. Animals sacrificed at 6, 12, and 18 months were excluded from the calculations.

Starr and Buck's model deviated substantially that of Hoel *et al.* because it did not show a linear relationship between formaldehyde-protein-DNA adduct concentration and tumor incidence. Instead, the multistage model

showed a strong cubic term with little contribution from other stages, a finding identical with that found for use of administered dose.

At concentrations of 0.1, 0.5, and 1 ppm, the delivered dose model consistently gave lower estimates of risk than more conventional risk assessment models. The predicted risks, based on the MLE were 35-53 times lower at 0.1 ppm, 53-101 times lower at 0.5 ppm, and 53-133 times lower at 1 ppm. The probabilities of a cancer occurring based on the MLE for "delivered" dose at 0.5 ppm were 9.8×10^{-10} (logit), 4.3×10^{-9} (Weibull), and 5.9×10^{-9} (multistage). Corresponding figures at 1 ppm were 2.2×10^{-8} , 7.1×10^{-8} , and 4.7×10^{-6} , respectively. (The Starr and Buck model must predict lower risks than the other models at 0.1 and 1 ppm because of the assumption that D is always 1.1 percent of A at levels below 2 ppm. The differences in predicted low dose risk simply reflect differences between the mathematical models.)

The FI: their consultant, Dr. Robert Sielken [Ex. 45-5D]; and the Chemical Manufacturers Association, (CMA) [Ex. 55], supported use of Starr and Buck's "delivered dose" model for predicting cancer risk in humans. This approach was also endorsed by the Office of Management and Budget (OMB) [Ex. 80-261].

Considerable controversy has surrounded the use of the Starr and Buck analysis for human risk assessment. EPA, in their report "Preliminary Assessment of Health Risk to Garment Workers and Certain Home Residents from Exposure to Formaldehyde, the CPSC in their comments to HUD regarding quantitative risk assessment, and OSHA in the December 10, 1985, proposal rejected the use of this pharmacokinetic model as "premature" [50 FR 50456].

Dr. Starr commented that more generally used models for quantitative risk assessment contain many of the same limitations raised as criticisms of his method [Tr. May 9, 1986, p. 137]. OSHA agrees; great uncertainty, of necessity, is linked with any low dose risk assessment, especially when the data in the observable region of the dose response curve is nonlinear, as it is for formaldehyde. However, assumptions specific to the Starr and Buck model, and not to other risk assessment models, have also been widely criticized.

Starr and Buck assumed that covalent binding resulting from two 6-hour exposures could be used as a surrogate for a 2-year bioassay. This assumption has been criticized because damage to the nasal epithelial cells ceased long

before tumors became evident [Exs. 70-39; 73-149; 85-89].

The model also assumed that the formaldehyde-protein-DNA complex identified by Casanova-Schmitz *et al.* [Ex. 62] was the sole product responsible for nasal tumor induction. This assumption has been called speculative [Exs. 56; 85-89], and OSHA agrees, although it is possible that the complex identified by the CIIT investigators might be responsible for the initiation of cancer.

Serious reservations have been expressed by scientists who doubted that information on DNA binding, applied without validating that it provides an adequate measure of carcinogenic response, is in the best interest of public health protection [Ex. 56; Tr. May 15, 1986, pp. 98-101, 194].

The pharmacokinetic model has also been challenged as inappropriate for formaldehyde. Formaldehyde is the biologically reactive agent, and it does not require activation to cause cancer, the phenomenon that the Hoel model addresses [Ex. 56, p. 13]. This serious problem is also unique to the Starr and Buck risk assessment.

When EPA's Office of Toxic Substances presented its draft risk assessment on formaldehyde [Ex. 73-149] to its Science Advisory Board, the SAB criticized it as scientifically inadequate because it did not provide an analysis of the pharmacokinetic information [Ex. 85-89, p. 2-1]. Consequently, EPA assembled scientists to conduct an in-depth review of the information to determine if it was useful for assessing human risk from exposure to formaldehyde.

The seven member team of experts in metabolism, DNA adducts, and statistics held a meeting on December 2 to 3, 1985. Representatives from the CIIT participated, but CIIT disagreed with the conclusions of the Expert Review Panel.

The Expert Panel determined that evidence presented by CIIT [Ex. 62] was suggestive, but not definitive, regarding assumptions used to distinguish between metabolically incorporated and crosslinked formaldehyde [Ex. 85-89, p. 3-1].

The Expert Panel raised another question regarding the relevance of the DNA binding data which appears to address a fundamental weakness:

In view of the established temporal changes in cell proliferation as well as the replacement of respiratory epithelial cells by squamous cells during chronic exposure, there is some question whether the results of the acute labeling studies will accurately reflect events occurring during longer-term exposures.

This is particularly important when it is considered that squamous cell carcinoma does not develop until 11 or 12 months into the chronic study and that a large percentage of DNA protein crosslinks are subject to relatively rapid repair [p. 3-3].

The CIIT investigators contended that covalent binding studies in normal respiratory epithelial cells are highly relevant to risk under normal human exposure situations [Ex. 85-84, Appendix, p. 8].

The Expert Panel was aware of the CIIT's position but disagreed. The Panel felt that the extent to which formaldehyde-DNA interactions may differ in the course of chronic exposure is unknown and that the validity of the acute model to represent chronic lesions remains to be determined [Ex. 85-84, p. 3-3]. OSHA agrees with these positions.

The Expert Panel examined evidence that all crosslinked formaldehyde was present at the interface rather than in the aqueous DNA. The panel members felt that characterization of the interfacial-DNA fraction was absolutely necessary to validate its use as a biological dosimeter for determining cancer risk, and the panel concluded that CIIT had not documented their assertions regarding interfacial DNA [Ex. 85-89, p. 3-2].

The CIIT investigators provided additional information at a later date in their statement disagreeing with the Panel's conclusions [Ex. 85-89, Attachment A]. CIIT investigators conducted high pressure liquid chromatography (HPLC) analysis of the aqueous DNA samples that had been collected from the nasal respiratory epithelium of rats exposed to 0.3, 2, or 6 ppm of labeled formaldehyde. For interfacial DNA, only a 6-ppm sample remained from the original study (see Ex. 62). Most of the radioactivity in aqueous DNA eluted at the positions of the normal deoxyribonucleosides, deoxyadenosine (dAdo), deoxythymidine (dTd), and deoxyguanosine (dGuo) implying that the labeling was primarily caused by metabolic incorporation.

In two of the three samples, small amounts of radioactivity eluted prior to the major peaks. While the investigators were unable to identify the substance represented by this peak, they believed that minor peaks were due to contamination of DNA with RNA.

In the single interfacial DNA sample from rats exposed at 6 ppm, a peak having an enhanced $^3\text{H}/^{14}\text{C}$ ratio eluted very early in the chromatogram. According to the authors:

Such a peak could be incompletely digested DNA containing covalently bound formaldehyde * * * This interpretation is, of

course, tentative, and additional studies are needed to test this hypothesis [Ex. 85-89, Appendix 7, pp. 1-5].

To OSHA, it seems essential that this chemical be identified and that its presence at other concentrations be shown if the CIIT expects the scientific community to accept their data as representing a biological dosimeter for formaldehyde's carcinogenicity. Furthermore, the same type of information would be needed for other time periods, not just for 12 hours of exposure. Should this additional information be available, questions would still remain regarding reproducibility of the results, the sensitivity of the method to changes in technique, and the relevance of the measure to the expression of cancer. Given the fact that not all persons who participated in the rulemaking on formaldehyde conceded the relevance of the animal bioassay results replicated in independent laboratories as predictive of human cancer risk, OSHA does not anticipate widespread acceptance of formaldehyde-DNA-protein complexes as a measure of human cancer risk at any time in the near future. Some participants combined positions rejecting the validity of the animal data as it applies to humans while at the same time recommending the use of the pharmacokinetic model to predict human risk. To OSHA, this is a fundamentally contradictory approach which accepts mutually exclusive conclusions.

EPA's Expert Panel gave alternative explanations for the results seen by the CIIT scientists. As an example, they noted that physiological and biochemical defense mechanisms could become less efficient causing DNA-protein crosslink formation to increase disproportionately (an alternative suggested by data on mucociliary clearance). Also, the disproportionate increase in $^3\text{H}/^{14}\text{C}$ ratio with increase in formaldehyde concentration might be due to artifactual disturbances or cell death.

At any rate, OSHA believes that the observation of covalently bound formaldehyde in animals exposed twice at 2 ppm [Ex. 85-84, Appendix, p. 18], a concentration that failed to show malignant nasal tumors in the rat bioassay, is significant to human risk. This, like the information on cytotoxicity, indicates to OSHA that 2 ppm should not be considered a "no-effect" level.

The Expert Panel encouraged CIIT's efforts as a first step to introducing intracellular dosimetry into the risk assessment process. However, they concluded:

At its present level of development and validation * * * the study does not represent an adequate basis for quantitative risk assessment. First, the problem of proper validation of the experimental methodologies must be accomplished * * * The evidence is not sufficiently strong at this time to reject the linear dose extrapolation model. Second, the selection of a single intracellular target is complicated by the nature of binding processes with DNA and could be augmented appropriately by the additional analysis of binding to intracellular proteins. Third, and perhaps most important, the selection of the acute model may not be entirely appropriate since it is the chronic dosimetry that is most relevant to risk assessment [p. 3-9].

OSHA's Conclusions Regarding the Pharmacokinetic Model: The HPLC analysis recently conducted by CIIT gives credence to the possibility that the substance identified in the interfacial layer may be related to the initiation of formaldehyde carcinogenesis. The Casanova-Schmitz and Heck study [Ex. 62] coupled with this information is the most convincing evidence available to date to suggest a mechanism by which formaldehyde might initiate cancer in target cells. There is strong evidence from human and animal studies, however, backed by other short-term test data, that formaldehyde can act at more than one stage in the carcinogenesis process. Indeed, reversibility of lesions in the bioassay animals when their exposures were terminated after two years strongly suggests that formaldehyde is a late-stage carcinogen. The DNA binding data, based on a 2-day experiment cannot take these late stage changes into account; at best it can predict the role of formaldehyde as an initiator of cancer.

The investigators, and Starr and Buck in their related risk assessment, pay great attention to the finding that the amount of covalently bound material, in nmol/mg DNA, divided by the airborne formaldehyde concentration, while constant at airborne concentrations above 6 ppm, decreases significantly at 2 ppm. This might suggest that protective mechanisms at 2 ppm prevent formaldehyde from reacting as efficiently with DNA as it does at high doses. If the DNA adduct/crosslink is related to the cancer induction mechanism, then less cancers should also be expected to occur at low doses than would be predicted from high-dose data. This prediction is experimentally unverifiable because less than one squamous cell carcinoma per 200 rats must be predicted by either model to fit the available bioassay data. This incidence rate is too low to provide

experimental verification of either set of assumptions.

A second result is not emphasized by the investigators. At 6 ppm the concentration of covalently bound DNA is 0.233 nmol/mg DNA; at 15 ppm it is 0.631 nmol/mg DNA [Ex. 62]. While the concentration of covalently bound formaldehyde divided by airborne formaldehyde remains constant, 0.04 nmol/mg DNA/ppm, the same calculation based on cancer incidence in the CIIT rats changes from 0.3 tumors/ppm at 5.6 ppm to 7.2 tumors/ppm at 14.3 ppm. Thus, the dramatic increase in cancer incidence from 5.6 to 14.3 ppm, approximately 2 to 50 percent, cannot be accounted for by a corresponding increase in DNA adduct/crosslink formation.

Consequently, the information on cancers induced in the 6 to 15 ppm region is inconsistent with the DNA binding results, which indicate that a 3-fold increase, or about 6 of the 103 cancers in the high-dose group may have been caused by the increase in DNA binding. This is one of many reasons to believe that formaldehyde can act as a carcinogen at more than one stage of the multistage model of carcinogenesis.

The ability to develop an animal model, based on only two days of exposure, to predict carcinogenic activity presents a tantalizing alternative to conducting a 2-year animal bioassay using standard protocols and good laboratory practices. This alternative would be more attractive if short-term results can be applied quantitatively to predict cancer risk in humans. Unfortunately, the 2-day DNA-protein binding study, while concordant with the finding that formaldehyde is a carcinogen, is a new technique, lacking validation and appearing inadequate to assess the complex interactions that lead to cancer induction from formaldehyde exposure.

As presently constituted, the pharmacokinetic model is greatly limited by the paucity of data identifying DNA protein-formaldehyde cross-links, and OSHA concludes that it cannot be presumed to predict overall human cancer risk resulting from long-term repeated exposures to formaldehyde.

Summary of Information on Cancer

Formaldehyde is an extremely reactive molecule which accounts both for its importance as an industrial chemical and its toxic effects in humans. Its ability to bind to free amino groups causes formaldehyde to be able to react with single-stranded DNA and crosslink DNA and protein as well as cause DNA strand breaks. This evidence alone would be sufficient to suggest that

formaldehyde has carcinogenic potential [Ex. 139A-1, Attachment VI, p. 26].

Since OSHA's proposal was published in December 1985, substantial evidence regarding formaldehyde's potential to cause cancer in humans has become available. Blair *et al.* found an excess of lung and nasopharyngeal cancers in a large cohort mortality study of U.S. workers exposed to formaldehyde along with other chemicals [Exs. 156-A4; 200-4]. Although the authors' felt their study showed little evidence that formaldehyde was a lung carcinogen since they failed to find a dose-response relationship between formaldehyde exposure and lung cancer risk, few scientists who reviewed this study agreed with the authors' conclusions. There was a strong, although not unanimous, consensus in comments received by OSHA that this study demonstrated excesses of both lung and nasopharyngeal cancer. After carefully reviewing the data, including the authors' publications, Blair and Stewart's testimony [Tr. May 8, 1986, pp. 163-328], the testimony and comments of other witnesses (especially Drs. Landrigan and Schneiderman, NIOSH, the UAW, and the FI), the transcripts and exhibits from a House Subcommittee hearing on the conduct of the study [Ex. 158], and reanalyses of the data submitted by Sielken [Exs. 104-F; 104-FI; 134], Park [Exs. 108-D; 146-B; 146-D], and Sterling and Weinkam [Ex. 200-1], OSHA concludes that this study showed an excess of both lung and nasopharyngeal cancer in workers, and that formaldehyde exposure most likely played a role in these cancers.

Additional information from recently published studies also shows an excess of nasal cancers in workers with formaldehyde exposure [Exs. 173: 201-11A; 202], nasopharyngeal cancers in long-term mobile home residents [Exs. 200-3; 201-3A], and possibly buccal cavity cancer in garment workers, who, unlike the other groups studied were primarily women [Ex. 98-A]. Combined effects of exposure to formaldehyde and wood dust may be multiplicative, especially with regard to adenocarcinomas (see Ex. 201-11A). Formaldehyde exposure was strongly associated with squamous cell carcinomas of the human nasal cavity. Squamous cell carcinoma was also the predominant nasal tumor seen in rats.

In addition to reacting with DNA [Ex. 70-25], formaldehyde reacts with free amino groups in cells, including glutathione. The reaction product serves as the substrate for the enzyme, formaldehyde dehydrogenase, which converts formaldehyde to formic acid. Formic acid does not display the

genotoxic and carcinogenic properties of formaldehyde. This observation is consistent with the failure to find DNA-protein-formaldehyde crosslinks in the bone marrow of rats that inhaled formaldehyde [Exs. 62; 85-107]. Furthermore, neither brain cancer nor leukemia were seen in animals exposed to formaldehyde for up to 24 months at 14.3 ppm [Exs. 12; 43]. These results suggest that formaldehyde "does not reach distant sites at levels capable of substantially increasing the levels produced by normal intermediary metabolism" [Ex. 139-A-1, Attachment VI, p. 27].

In contrast to the results in animals, humans who handle preserved tissue have shown an increased incidence of brain cancer and possibly leukemia [Exs. 42-81; 42-124; 73-42; 73-43]. It was argued that these excesses represent social class bias [Tr. Feb. 15, 1985, pp. 621-627; Ex. 73-81C], but access to health care does not completely account for the findings. The epidemiologic studies of persons who handled preserved tissue focused on older groups than the studies of industrial workers [Ex. 96]. The age difference and expected differences in smoking patterns make assessment of the role of formaldehyde in causing cancer at sites remote from the site of application difficult. It is even possible that indirect mechanisms such as alterations of the immune system [Exs. 25-19; 73-14], could affect remote-site cancer rates.

At this point, there is insufficient information available for OSHA to reach a definitive conclusion regarding formaldehyde's role in brain cancer and leukemia. OSHA agrees with NIOSH's statement that "the results of individual studies suggest that formaldehyde exposure may be associated with increased risk of lung cancer, brain cancer, and leukemia, although a plausible carcinogenic mechanism for the two latter findings is not clear" [Ex. 98, p. 5]. Because brain cancer and leukemia could not be linked to formaldehyde exposure by plausible biological mechanisms, OSHA excluded this information from its quantitative assessment of risk of cancer. If cancers at these sites are related to formaldehyde exposure, OSHA's assessment probably underpredicts human cancer risk.

A number of studies now available only indirectly link formaldehyde exposure to cancer excesses (e.g. exposure to resins and glues, exposure in trailers). There are also confounding exposures in some populations (e.g. wood dust), and the potential interaction between smoking and formaldehyde,

which demonstrates the properties of both an initiator and a late-stage carcinogen, is unknown. If the combined effects of smoking and formaldehyde exposure are more dangerous than exposure to either of these carcinogens in isolation, formaldehyde-exposed workers who smoke would be at higher risk than others who do not smoke, which would obscure any dose-response relationship between formaldehyde and respiratory cancer. For these reasons, a direct causal relationship between formaldehyde and excess respiratory cancer risk can be inferred but not proven absolutely in any of the human studies available. The one potential carcinogen that all of the positive epidemiologic studies have in common, however, is formaldehyde. Thus, the evidence that formaldehyde is a probable human carcinogen is substantial. Evidence that formaldehyde caused preneoplastic lesions in workers, similar to those seen in rodents which developed cancer [Exs. 12; 85-50], is concordant with this conclusion.

That formaldehyde is a demonstrated carcinogen in animals is undisputed [Exs. 13; 70-56; 90; 98; Tr. February 13, 1985, pp. 89-118; Tr. May 12, 1986, pp. 94, 103]. In chronic bioassays, two independent studies have shown a dose-related excess of nasal carcinomas in the same strain of rat [Exs. 12; 42-131; 73-146]. These results have also been replicated in a third study at a single dose in a separate strain of rats [Exs. 42-3; 42-4]. Concordant evidence is available to demonstrate biological plausibility from studies of cytotoxicity, metabolism, *in vitro* genotoxicity, and evidence of DNA-binding. Nasal cancer has also been demonstrated in mice [Ex. 42-131] although not in hamsters [Ex. 42-33]. The results in mice, which show fewer cancers than rats for the same airborne concentration, are biologically plausible and consistent with experimental design. They do not necessarily demonstrate a marked species susceptibility. A definitive statement regarding the hamster's susceptibility to formaldehyde cannot be made. The primate (monkeys) responds to formaldehyde exposure more like the rat, however [Exs. 42-16; 42-104], suggesting that the rat is a more appropriate model for human risk than the hamster.

In its quantitative risk assessment, OSHA placed primary emphasis on the CIIT rat data and sought concordance with its low dose estimates from human evidence of lung, nasopharyngeal, and nasal cancer. Potential systematic errors in assessing historical exposures [Exs. 144-A; 146-A] and the lack of

meaningful exposure data generally found for the case-control studies that must be used to detect rare forms of cancer limit the usefulness of the human data in predicting risk of exposure to formaldehyde [Ex. 105-A, Att. IV].

All quantitative risk assessments conducted to date have used the CIIT rat data to predict risk although a few have also attempted to include other information as well [Exs. 45-5, 80-161]. As Rodericks and Turnbull pointed out, there are several advantages to use of the CIIT rat data set [Ex. 139-A-1, Attachment VI, pp. 37-38]. This data set provides the best estimation of the relationship between dose and response since an increase in tumor incidence was seen at more than one dose level tested. Also, subsequent work conducted by the CIIT on physiological and biochemical effects of formaldehyde at the same dose levels in rats assists in analysis of the relationship between formaldehyde exposure and cancer. According to Rodericks and Turnbull, "use of these data is likely to provide the scientifically most credible dose-response assessment" [Ex. 139-A1, Attachment VI, p. 38].

It has been a long-standing assumption in toxicology that effects in humans can be inferred from effects in animals and the principle of extrapolation of animal data to humans has been widely accepted in the scientific and regulatory communities [Ex. 139-A1, Attachment VI, p. 43].

Based on a review of mathematical models available for assessing the effects of formaldehyde exposure, OSHA concluded that the multistage model provides the most defensible description of human risk because it is biologically plausible and not likely to underpredict risk. While certain other models, such as the logit and Weibull models and the additive multihit model provide similar estimates of risk for formaldehyde, their theoretical basis does not fit what is known regarding formaldehyde's possible mechanisms of carcinogenic action.

The weight of the evidence from all data on humans, animals, and short-term tests suggests that formaldehyde probably acts as a complete carcinogen, capable of both initiation and late-stage carcinogenesis. Consequently, formaldehyde may react quite differently at different sites in the respiratory system. For rare forms of cancer, background additivity probably has minimal influence on cancer rates. In contrast, lung cancer is a common cause of death in humans. If formaldehyde can react at more than one stage, as is suspected, it will be able

to move cells that have completed some preneoplastic transformations prior to exposure to formaldehyde up the chain toward the completion of the cancer process. Thus, if formaldehyde causes lung cancer, it will also cause exposed individuals to develop lung cancer earlier.

Many uncertainties enter into risk analysis, partly because it is inherently difficult to extrapolate risks from animals to humans. Uncertainties include dose-rate effects, probably caused by alteration of mucociliary clearance and cell proliferation, and inferences that must be made to permit species-to-species extrapolation. More uncertainties are introduced because many humans are exposed to formaldehyde-bearing particles which may release formaldehyde when they contact the moist surfaces of the respiratory system, thus increasing the person's exposure.

Risk assessment for formaldehyde is complicated because of differences between the rodent and human respiratory systems [Ex. 139-A-1, Appendix VI, p. 43]. In deriving comparative human dose measurements, the dose at the site of contact might be more important in predicting risk than the dose averaged over body weight or total body surface area [Ex. 139-A-1, Appendix VI, p. 44]. One approach would be to normalize human and rodent exposure measures in the nasal cavity [Ex. 139-A-1, Appendix VI, p. 44]. OSHA rejected this approach [Ex. 43] because little is known about the relative surface areas of the human and rodent nasal passages, because humans are not obligated to breathe through their noses (indicating for some humans that the nose is bypassed as a site of contact), and because humans (but not rats) appear to be susceptible to developing lung cancer from formaldehyde exposure.

Accurate inferences of risk in humans derived from data in animals require evaluation of interspecies differences that might influence susceptibility [Ex. 139-A-1, Appendix VI, p. 43]. In the absence of comparative data on pharmacokinetics and metabolism between rodents and man, OSHA assumed that the human is equivalent to the rat for scaling purposes. This source of uncertainty was thought to be conservative in the proposal; however, human evidence of cancer risk now verifies that the assumption is justified. There is clearly substantial evidence to support OSHA's scaling decision in this case; as the court has stated, the test of substantial evidence is not "proof positive". (See *Public Citizen Health*

Research Group v. Tyson, 796 F2d at 1495.)

Formaldehyde impaired mucociliary clearance in humans [Ex. 42-10; 42-130] and animals [CIIT]; this effect has been seen following minimal human exposures to formaldehyde (1.8 ppm for 5 hours in volunteer subjects) [Ex. 42-10]. Because mucociliary clearance may serve as a protective mechanism against cancer, and because mucous flow also assists in the removal of other toxic chemicals and viruses, changes in mucociliary clearance should be viewed seriously, possibly as precursors to a material impairment of health.

Human Versus Animal Data: When the CIIT announced preliminary results of its carcinogenicity bioassay in the fall of 1979, interest was generated in examining the effects of formaldehyde on cancer mortality rates in occupationally exposed humans. While some quick surveys were made within months (see for example Ex. 42-81), large epidemiologic studies can take many years to complete, and some of the studies generated as a result of the CIIT rat data only became available after OSHA's proposal was published.

In the interim, controversy has surrounded OSHA's and other agencies' regulatory actions on formaldehyde regarding the proper weight to assign the human epidemiological evidence in light of the strong evidence in animals.

In 1981, Dr. Arthur Upton, the former Director of NCI, articulated the position of scientists regarding the carcinogenicity of formaldehyde in a letter addressed to the heads of various Federal agencies [Ex. 73-27].

My colleagues * * * share with me the conviction that formaldehyde is decisively carcinogenic in animals, and with the evidence for its genotoxicity, it is likely that formaldehyde is a human carcinogen. While the relative potency for animals and man is uncertain, we believe it would be a mistake to ignore the evidence for carcinogenicity on the grounds of negative epidemiology which at best can only set upper limits to the carcinogenic potency in man.

In a 1984 editorial in the *American Journal of Industrial Medicine*, Dr. Myra Karstadt of the Mt. Sinai School of Medicine reiterated this position:

Although epidemiological studies are inconclusive * * * the animal data are in and of themselves dispositive of the issue of whether formaldehyde is a carcinogen, and should be sufficient grounds for regulatory action on the chemical [Ex. 73-27, p. 487].

Dr. Phillip Landrigan, Professor of Community Medicine at the Mount Sinai and former Director of the epidemiologic studies program at NIOSH, expresses a similar position at OSHA's hearings:

It is my opinion and the opinion of the American Public Health Association that formaldehyde is a proven animal carcinogen. On that basis alone, therefore, formaldehyde ought to be regarded as though it were a human carcinogen [Ex. 100, p.6].

Subsequently, after evaluation of the new epidemiologic information, Dr. Landrigan modified his previous position:

(T)aken *in toto*, the data from these [epidemiologic] reports and the data from the two animal studies submitted previously indicate clearly that formaldehyde is toxic and carcinogenic to the respiratory tract. I disagree strenuously with the attempt by the Formaldehyde Institute to dismiss these findings as "spot excesses." To the contrary, I see in these data a consistent pattern of respiratory carcinogenesis in species ranging from the rat to the human [Ex. 201-1, p. 2].

At OSHA's hearings, Mr. Richard Lemen indicated that NIOSH's position since 1981 has been that formaldehyde should be regarded as a potential occupational carcinogen. The basis of NIOSH's 1981 position was "the significant excesses of squamous cell carcinomas of the nasal cavity found in both male and female Fischer 344 rats, the occurrence of squamous cell carcinomas in C57BL/6 x C3HF1 male mice, and the evidence of a statistically significant excess of squamous cell carcinomas in the nasal cavities of male Sprague-Dawley rats." According to Mr. Lemen:

This evidence alone is sufficient to classify formaldehyde as a category I carcinogen as described in the OSHA Cancer Policy (29 CFR 1990) [Ex. 98, p. 5].

Mr. Lemen clarified that NIOSH's present position regarding formaldehyde is also based on epidemiologic evidence. He stated:

The NIOSH recommendation is also based on our evaluation of the recent National Cancer Institute epidemiologic study of formaldehyde-exposed workers. The NIOSH evaluation of the NCI study concludes that there is evidence of increased carcinogenicity among formaldehyde-exposed workers which cannot be readily discounted by a lack of an exposure response trend [Ex. 98, pp. 5-6].

Dr. Philip Cole, an epidemiologist who testified for the FI, contended that animal studies have little relevance to humans and that variations in the epidemiologic studies "are consistent with random effects and do not detract from the pattern of no excess of any specific form of cancer, much less of cancer in the aggregate" [Ex. 118, pp. 1-2].

Because formaldehyde did not cause nasal cancer in hamsters, Dr. Cole believed that "there is no theoretical basis for thinking that human beings are

particularly susceptible" [Ex. 118, pp. 1-2].

OSHA has rejected the argument that the hamster data provide evidence of differences in species susceptibility to formaldehyde because of the limited nature of the study and the cellular changes reported in the animals' nasal cavities, which were consistent with the more severe effects seen in rats and mice. Even if there are species differences, OSHA must give great weight to the overall evidence that is derived from examining the total picture in man. As Dr. Fairchild of NIOSH described, replication of testing is sought in animal bioassays, not to decrease the likelihood that a noncarcinogen will be treated as a carcinogenic substance in humans, but to ensure that the inherent insensitivity of animal studies does not lead to failure to detect a human risk [Ex. 144-Att. I].

The position advocated by Dr. Cole, which rejects the use of animal data to infer cancer risk in man, is contrary to prudent public health policy because it advocates exposing human to chemicals suspected of being toxic. Consequently, regulatory agencies often must act, as has been done in the past, on the basis of strong animal evidence, even though there is a lack of definitive human evidence, especially when effects have a long latent period before their manifestation. Indeed, the Occupational Safety and Health Act contemplates that the Agency will in many cases rely on animal evidence, and implicitly endorses this approach by directing that Agency action in regulating toxic substances be based on "the best available evidence."

Dr. Cole's statement reflects some industry comments [Tr. May 12, 1986, p. 96] which argued that animal data should not be extrapolated to humans and that there are weaknesses in individual epidemiologic studies such that, one-by-one they do not present credible evidence [Ex. 201-8]. This position was not supported by the testimony of any other witnesses or by comments to OSHA's formaldehyde record: it was also not supported by publications in the open literature. This position is also contrary to the AGGIH classification of formaldehyde; the AIHA's guidelines for formaldehyde; and recent actions taken by EPA, which classified formaldehyde as a category B(1) carcinogen, and by IARC, which upgraded the classification of formaldehyde from an animal carcinogen to a substance that is a probable human carcinogen.

The position that each epidemiologic study should be viewed in isolation is

also contradicted by the decision of the U.S. Court of Appeals for the District of Columbia Circuit regarding the standard for occupational exposure to ethylene oxide. The court stated:

AEOU attacks each piece of evidence, suggesting that no individual piece proves a relationship between ETO exposure and various adverse health effects. This approach disregards the marginal contribution that each piece of evidence makes to the total picture. While some of OSHA's evidence suffers from shortcomings, such incomplete proof is inevitable when the Agency regulates on the frontiers on scientific knowledge. 796 F.2d at 1494-1495.

* * * The scientific evidence in the instant case is incomplete but what evidence we have paints a striking portrait of serious danger to workers exposed to the chemical. When the evidence can be reasonably interpreted as supporting the need for regulation, we must affirm the agency's conclusion, despite the fact that the same evidence is susceptible of another interpretation. *Public Citizen Health Research Group v. Tyson*.

In stressing that "incomplete proof is inevitable when the Agency regulates on the frontiers of scientific knowledge", the court cited another decision regarding an EPA rule (*Ethyl Corp. v. EPA*, 541 F.2d 1, 37-38 (D.C. Cir.) (en banc (footnote omitted)), *cert. denied*, 426 U.S. 941 (1976)):

Contrary to the apparent suggestion of some of the petitioners, we need not seek a single dispositive study that fully supports the Administrator's determination. Science does not work that way; nor for that matter, does adjudicatory fact-finding. Rather, the Administrator's decision may be fully supportable if it is based, as it is, on the inconclusive but suggestive results of numerous studies. By its nature, scientific evidence is cumulative; the more supporting, albeit inconclusive, evidence available, the more likely the accuracy of the conclusion * * *. Thus, after considering the inferences that can be drawn from the studies supporting the Administrator, and those opposing him, we must decide whether the cumulative effect of all this evidence, and not the effect of any single bit of it, presents a rational basis for the * * * regulations.

OSHA did not rely on single studies or evidence from any one species in reaching its decision regarding the carcinogenic potential of formaldehyde. OSHA's conclusions, instead, are based on the overall picture painted by viewing each piece of information available. OSHA believes that this position is consonant with judicial interpretations of its authority under the Occupational Safety and Health Act and that it represents firmly established scientific principles for establishing the toxic effects of chemicals. For example, the OSTP report on chemical carcinogens pointed out that decisions

on the carcinogenicity of chemicals in humans should be based on analysis of all relevant data, whether they are indicative of a positive or negative response, and should be based on sound biological and statistical principles [Ex. 73-90, p. 9]. OSHA also finds that these decisions are consistent with the Cancer Policy. However, reliance on this regulation was unnecessary to OSHA in reaching its conclusions on formaldehyde.

The OSTP report recognized that instances occur when animal data indicate that a substance is carcinogenic, but epidemiological evidence is less conclusive or negative. Regarding the use of negative human studies, the OSTP stated:

A high quality negative epidemiological study, while useful, cannot prove the absence of an association between chemical exposure and human cancer. Within the scope of the study, specifically for the populations studied (including concomitant) exposures, for the levels of durations of exposure to the agents evaluated and for the time assessed following exposure, a likely range can be determined for the estimates of risk and the statistical likelihood of the study to detect an effect can be assessed [Ex. 73-90, p. 9].

By following the principles articulated by the OSTP, OSHA determined that the cumulative evidence from each epidemiologic study, and not the evidence from any one study is concordant with the animal evidence; taken as a whole this information constitutes substantial evidence to support a conclusion that formaldehyde poses a carcinogenic risk to workers. In reaching its decision regarding the epidemiologic data, OSHA weighed several factors: exposures to formaldehyde in the past have been limited because of its severe irritation at high levels; the vast majority of the epidemiologic studies available lacked sufficient power to detect all but enormous increases in cancer mortality; and the studies that were most likely to yield evidence of cancer did so. OSHA would regard formaldehyde as a potential occupational carcinogen on the basis of the animal data regardless of the epidemiologic findings. The concordant nature of the findings, however, increase the agency's confidence in its analysis.

VII. Significance of Risk

OSHA's decision to issue a new or revised standard is grounded in its statutory mandate as construed through judicial review. In the Benzene case (*Industrial Union Dept., AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607 (1980)), the Supreme Court held that, in regulating toxic materials, OSHA must

make a determination that a "significant" health risk exists and that a new or revised standard will substantially reduce or eliminate that risk.

In the Benzene decision, the Supreme Court indicated when a reasonable person might consider the risk significant and take steps to decrease it. The Court stated:

It is the Agency's responsibility to determine in the first instance what it considers to be a "significant" risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it. (*I.U.D. v. A.P.I.*, 448 U.S. at 655).

The Court stated that "while the Agency must support its findings that a certain level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations." The Court added that the significant risk determination required by the OSH Act is "not a mathematical straight jacket," and that "OSHA is not required to support its findings with anything approaching scientific certainty." The Court ruled that "a reviewing court [is] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge [and that] * * * the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection" (448 U.S. at 655, 656).

During the last few years, OSHA has produced risk assessments for making significance of risk determinations for several toxic substance standards. Two standards that have been reviewed by the courts have been upheld; the inorganic arsenic standard where human studies were the basis for the risk assessment and ethylene oxide where animal studies provided the primary basis for the risk assessment [*ASARCO v. OSHA*, 746 F.2d 483 (9th Cir., 1984); *Health Research Group v. Tyson*, 796 F.2d 1479 (D.C. Cir. 1986)]. OSHA's approach in making the significance of risk determination for formaldehyde is consistent with that used for these other toxic substance standards.

Considerable attention in this rulemaking has been given to the quantification of the cancer risk associated with formaldehyde exposure. OSHA believes that it is appropriate to quantitatively estimate risks where possible, but is concerned, however, that too much importance may be given to numerical estimates without due consideration of the data used to make the estimates. In order to give appropriate weight to the scientific evidence in the record, OSHA considered a number of factors as part of the overall significant risk determination. These included the type of risk presented, the quality of the underlying data, the reasonableness of the risk assessments, the statistical significance of the findings and the magnitude of risk (see, for example, Arsenic, 48 FR 1864, January 14, 1983).

The epidemiologic and toxicologic evidence discussed in Section V of this preamble (Health Effects) clearly indicate that formaldehyde exposure causes several adverse health effects. These include cancer, respiratory and skin irritation and sensitization, and acute effects. OSHA's conclusions are based upon many well conducted studies, both in humans and in animals. Further, OSHA was able to quantify the risks for cancer and make semi-quantitative risk estimates for irritation. These estimates indicate that OSHA's current standard is inadequate. OSHA has concluded that the reduction of the PEL from 3 ppm to 1 ppm as an 8-hour time-weighted average is reasonably necessary and appropriate to reduce the significant risks associated with exposure to formaldehyde. Reduction of the 10 ppm ceiling and 5 ppm peak to a single short-term exposure limit of 2 ppm is needed to lower the risk of cancer, to prevent severe sensory irritation, and to eliminate asthmatic responses.

In deciding whether to promulgate a complete standard or simply to alter the existing PELs, OSHA has also considered how provisions other than the PELs, including medical surveillance, environmental monitoring, housekeeping, emergency planning, posting of regulated areas, and training would further reduce the risks of exposure to formaldehyde. The risk of dermal irritation and sensitization, for example, is reduced primarily through provision of properly selected and adequately maintained personal protective equipment and clothing to prevent skin contact with irritating and sensitizing materials. Other provisions of the standard such as medical monitoring, housekeeping, and the

availability of wash facilities intertwine to further reduce the incidence of dermal diseases and disorders.

Quality of the Cancer Evidence: The formaldehyde record contains several studies regarding formaldehyde's ability to cause cancer. Long-term animal bioassay studies have made it clear that formaldehyde causes cancer in rodents. Short-term studies have corroborated the findings on formaldehyde's carcinogenicity and have enabled scientists to better hypothesize mechanisms of carcinogenic action. Studies in humans have shown positive findings consistent with other studies.

OSHA based its cancer risk assessment on the CIIT rat bioassay [Exs. 12: 42-131]. The study used good laboratory practices and had extensive and well conducted pathology. It also examined progression of lesions and conducted complementary clinical tests. Slides were made available to outside reviewers who agreed with the original findings. Given the difficulties inherent in conducting inhalation studies, the investigators were able to keep the exposures quite constant, and the exposures were thoroughly monitored, thus assuring a true measure of dose. The CIIT study contained an adequate number of animals and three test groups plus the control group. The exposure levels were well-chosen so that an adequate response was obtained without excessive morbidity. One commenter [Ex. 63] suggested that more animals could have been tested in the midrange group to obtain a better statistical confidence, but this comment was made in hindsight as a way that would improve statistical analysis and OSHA does not believe it suggests that the study is flawed. As a consequence, the CIIT study was more sensitive than studies conducted under the government's own National Toxicology Program and, therefore, it is better able to predict risks. OSHA is not alone in the opinion that the CIIT study was excellent and other Agencies and groups, such as the EPA and the Formaldehyde Institute, have used the CIIT rat study as the basis for quantitative risk assessments [Exs. 42-29; 45-1; 69-15; 73-149; 86-26; 114; 138-C].

The CIIT also performed a high quality mouse study confirming formaldehyde's carcinogenicity in a second species [Exs. 12: 42-131]. This study also used good laboratory practices and well conducted pathology. However, the exposure levels chosen for the study might have been too low because the mice did not develop a sufficient number of tumors to conduct a

good quantitative risk assessment. The apparent discrepancy between the rat tumor and mouse tumor incidence is explained by several well-designed experiments [Exs. 42-13; 69-23-A3; 69-23-C4; 70-29; 73-34]. These studies showed that the mouse, unlike the rat, reduced its breathing rate when exposed to formaldehyde and therefore the mouse's effective dose to the target site was relatively less than the rat. This finding was not controversial and provides a reasonable explanation for preference of the rat study for the quantitative risk assessment. Furthermore, when corrections for breathing rate differences are made for purposes of quantitative risk assessment, the mouse data fits the rat data.

The NYU rat bioassay [Exs. 42-3; 42-4] provides further evidence of carcinogenicity, but as described in the previous section, the pathology was not as extensive as that conducted in the CIIT studies and the dose was limited to a single level. Similarly, the rat study by Tobe *et al.* [Ex. 73-146] and the hamster study by Dalbey [Ex. 42-33] contained certain limitations that lessen their usefulness.

For most toxic substances, carcinogenesis testing in animals is supported by minimal research that helps to explain the bioassay results. This is not the case for formaldehyde. In contrast, extensive follow-up research performed by the CIIT helps to interpret the bioassay data and gives OSHA the confidence to rely more heavily than usually possible on arguments of biological plausibility in determining how quantitative risk estimates should influence OSHA's judgment regarding the need for a revised formaldehyde standard. In particular, OSHA believes that the cytotoxicity studies showing cellular turnover and the DNA adduct formation studies provide useful information which is concordant with a conclusion that formaldehyde is a substance capable of causing cancer.

There was considerable controversy surrounding the attempt to use DNA adduct formation in rats to predict human risk; OSHA does not believe, however, that this controversy negates the possibility of using the data qualitatively. In this regard, there was considerable agreement among participants that DNA binding studies provide information relevant to determining the carcinogenic potential of a chemical. Such information is not generally available for other substances. These studies were used by many participants, including OSHA, in

formulating the justification for this standard.

OSHA believes that the quality of the epidemiology studies is good, but not of the superior quality of the CIIT bioassay studies; nor was the quality of the epidemiology studies as good as those that OSHA used to justify the inorganic arsenic, asbestos, and benzene standards. In those three cases, OSHA believes that the epidemiology studies were exceptional.

Limitations in the epidemiological method are often due to lack of information available and are not necessarily due to a problem with the design of the study. In the case of formaldehyde, many well conducted studies exist. Several studies have adequate design and followup. However, factors, such as low exposure or short duration of exposure, make the risk observed sufficiently low so that it may be masked by the background cancer mortality rates. This is especially likely in the case of lung cancer, which has a high background rate. The Epidemiology Panel of the Consensus Workshop on Formaldehyde [Ex. 70-56] stated that epidemiology studies could detect lung cancer only through study of populations who experience high exposure levels.

The largest study of lung cancer in formaldehyde workers conducted to date was the cohort mortality study of Blair *et al.* [Ex. 156-A4]. OSHA believes that the Blair *et al.* study [Ex. 156-A4] was generally well done. It was a large study that included 10 different plants and many workers; the followup was good. The statistical analysis was adequate. Blair *et al.*'s use of multiple plants producing different products was intended to discount the chance that exposure to some other substance could result in a false positive. Since formaldehyde was the only chemical present in all of the worksites, there is a great degree of confidence that positive findings should be attributed to formaldehyde. Whereas most epidemiology studies do not contain exposure information, this study included exposure estimates for each worker in the cohort. However, workers' exposures tended to be low, greatly limiting the study's ability to detect an excess risk of cancer. Overall, material collected for the study contains a wealth of data for analysis, and the authors made these data tapes available to other investigators who requested them. These alternative analyses of the data were extremely useful to OSHA in its analysis of the study.

Blair *et al.*'s epidemiologic study and its accompanying exposure assessment were criticized during the rulemaking

proceedings; OSHA agrees with some of the criticisms, particularly with regard to the study's ability to demonstrate a meaningful dose-response relationship. Numerous epidemiologists criticized the authors' statement that there was little evidence of a cancer risk at the levels of exposure experienced by the workers in the study even though they agreed that the study was adequately designed and conducted (see, for example, the testimony of Dr. Schneiderman and NIOSH). In particular, the authors appeared to place far too much emphasis on their failure to find a dose-response relationship for lung cancer in light of the increased risk seen for lung and nasopharyngeal cancer coupled with the higher risk of lung cancer seen in workers with a long latency. Indeed, the authors later published a followup study indicating that they now agreed that exposure to formaldehyde in the presence of particles appeared to be associated with an excess risk of nasopharyngeal cancer [Ex. 200-4].

OSHA's interpretation of the information from the Blair *et al.* study is consistent with the OSPT Chemical Carcinogens document [Ex. 73-90, p. 59] and with NIOSH's analysis of the study [Ex. 144]. In this regard, the OSTP document represents a government-wide position paper on interpretation of carcinogenicity studies and associated risk. As envisioned in the OSH Act. One of the functions of NIOSH is to provide scientific support to OSHA in its regulatory efforts.

Statistical Analysis: Throughout the formaldehyde rulemaking, as with other OSHA rulemakings for toxic substances, statistical techniques were used to analyze the data and interpret the findings. Statistical analysis is useful in determining whether an observation was a result related to the conditions studied or whether the observation could have occurred by chance. The use of statistics is well defined when applied to experimental bioassays. For example, in the CIIT rat study, there was a significant increase in squamous cell carcinomas of the nasal cavity in both males and females exposed to formaldehyde at 14.3 ppm. Other malignant tumors did not occur in significant excess. In general, statistical analysis of the animal data by the scientists conducting studies of formaldehyde effects received little comment during the rulemaking. There was some disagreement among scientists regarding the use of statistical tests to determine the significance of results reported in epidemiological studies: the effects, however, were small in terms of interpreting the results and

there was virtually no impact on OSHA's analysis of the information.

Mathematical extrapolations must be used to make estimations of risk outside of the observed range in a study. This process of low dose extrapolation, described in the Quantitative Risk Estimate section of this preamble, also involves the use of statistical techniques, which received considerable comment in the rulemaking. OSHA believes that statistics are an important consideration in quantitative risk assessment, but that the application of statistical analysis for defining the dose-response relationship should be consistent with the underlying biological science. Therefore, OSHA prefers risk estimation models that have biological plausibility, such as the multistage model [Ex. 63] even when these models provide a statistically worse fit to the animal data than other, biologically less plausible models. Because of the extensive biological information available for formaldehyde, certain decisions regarding risk assessment were made on the basis of information other than the best statistical fit of the data. For example, in the Starr and Buck pharmacokinetic analysis, OSHA believes that a proportional model should have been employed, as recommended by Hoel *et al.* [Ex. 69-23B-4], in addition to the other models used to fit the data even though the fit of the proportional model may not have been as good as the other models.

In conclusion, the use of statistical techniques in the analysis of the human and animal studies has given OSHA considerable confidence in the finding that formaldehyde is a carcinogen. In the quantitative risk assessment, however, the use of information showing biological plausibility may be more important than exact statistical procedures.

Reasonableness of the Risk Assessment: A qualitative evaluation of OSHA's best estimate of risk indicates that the estimates are reasonable. OSHA has predicted that the cancer risk to employees exposed for a lifetime to formaldehyde at 3 ppm ranges from an MLE of 43 [Ex. 69-15] to an UCL of 1,819 [Ex. 69-15] cases of cancer per 100,000 workers. These estimates were based upon the CIIT rat study. Although there is always some uncertainty when extrapolating from rats to humans, the limited evidence available from available human studies indicates that the rat study does not overpredict risk. Use of epidemiology data in this way is consistent with the OSTP principles [Ex. 73-90]:

Within the scope of the study, specifically for the populations studied (including concomitant exposures), for the level and duration of exposure to the agents evaluated and for the time assessed following exposure, a likely range can be determined for the estimates of risk and the statistical likelihood of the study to detect an effect can be assessed [Principle 19, p. 9].

The Blair *et al.* study [Ex. 156-A4] could be used in this manner. OSHA concludes that the estimates of risk presented in this document are consistent with human experience.

OSHA's estimates reflect the consensus in the scientific community. All participants in the rulemaking used the CIIT rat study for quantitative risk estimation and nearly all used it exclusively. Many scientists preferred the use of the multistage model. OSHA's approach, on the whole, is consistent with typical quantitative risk estimates using bioassay data, and other estimates based on rat data, corrected for sacrificed animals, are also viewed by OSHA as potentially reasonable estimates of risk.

OSHA's risk assessment employs very little extrapolation beyond the exposure levels used in the CIIT study. OSHA's estimates are at 1 ppm and 3 ppm; the exposure levels in the study were 2 ppm, 5.6 ppm, and 14.3 ppm. This minimal amount of extrapolation is reasonable, particularly when one considers that extrapolation is sometimes made to two or three orders of magnitude when it is necessary.

This particular aspect of OSHA's analysis merits further discussion because of the large differences in risk estimates made by various participants. To a great extent, this difference is due to the nonlinearity of the tumor response in the rat study and the choice of different models to fit the data by the rulemaking participants. Biological explanations for the nonlinearity are based on the cell turnover studies, evidence of a dose-rate effect and disturbances of mucociliary clearance, and the DNA-adduct studies of the CIIT. Although this aspect of the toxicology is generally accepted by scientists, there is no consensus on the use of statistical models to describe these effects. Thus, the record contains several approaches to modeling the data, none of which make full use of the data.

Fortunately, OSHA does not need to make difficult scientific conclusions to support the formaldehyde standard. The Court stated that OSHA must make a finding that there is significant risk when complying with the existing standard. OSHA satisfies that requirement in this rulemaking because practically all risk estimates agree that

cancer risks at 3 ppm are significant. The Court further stated that the standard must substantially reduce the risk. All models in the record show a sharp decline of risk with decreasing dose.

In addition to the use of quantitative risk assessment to show significant risks at 3 ppm, several other studies reported adverse health effects when exposures were less than 3 ppm and approaching 1 ppm. These studies further support OSHA's conclusion that there is a need to revise the standard for formaldehyde.

The CIIT rat bioassay observed a statistically significant increased incidence of polypoid adenomas in the group exposed to 2 ppm [Ex. 12]. Although OSHA did not perform a quantitative risk estimate on these benign tumors, they have biological significance. Regardless of whether these tumors progress to malignancy, they are abnormal growths and their formation should be avoided.

A second study that observed adverse effects below 3 ppm is Blair *et al.* [Ex. 156-A4]. In its analysis of workers with a latency of greater than 20 years since first exposure, this study observed a statistically significant SMR of 135 for lung cancer in the worker group with less than 0.5 ppm-year exposure, a statistically significant SMR of 135 in the worker group with between 0.5 to 5.5 ppm-year exposure and an SMR of 132 for the worker group having greater than 5.5 ppm-year exposure. The Blair *et al.* study and Sterling and Weinkam's reanalysis also observed a statistically significant increase in nasopharyngeal tumors in workers exposed over 0.5 ppm [Ex. 200-1] and a significant dose response relationship. In another study by Edling *et al.* [Ex. 85-50], workers exposed at levels not exceeding 1.1 ppm had preneoplastic changes in the nose, which were evident in biopsy specimens. In addition, the CIIT observed increased cell proliferation and DNA-formaldehyde-protein adduct formation in the respiratory epithelia of rats exposed to 2 ppm.

These studies observing adverse effects below 3 ppm are direct evidence that the 3 ppm standard is inadequate.

Magnitude of Cancer Risks: In previous rulemaking, such as *Ethylene Oxide* (49 FR 25764) and *Arsenic* (43 FR 19584), OSHA has looked for guidance as to what constitutes a significant risk by evaluating existing risk rates found for other effects in various occupations. The estimated excess cancer mortality risk from exposure to formaldehyde at the previous PEL of 3 ppm for a working lifetime is at least as great as that posed by the risk for fatalities caused by accidents from all causes in industries

with an average risk (e.g. 202/100,000 for all manufacturing and 112/100,000 for service industries, based on 1985 rates for firms with 11 or more employees). Comparison of accidental fatalities with estimated deaths associated with exposure to a chemical should be made with care. Fatality rates used in the above examples consist of accidental deaths from all causes, but the cancer deaths predicted to occur from formaldehyde exposure are all from only one type of chemical exposure. Fatality rates are derived from data collected on actual deaths; cancer deaths are estimated from animal studies and are inherently less certain. Fatalities from accidents occur immediately; cancer deaths occur after repeated exposure and a considerable latency period. Since virtually no information is available regarding chronic occupational illnesses, fatality rates, even though they may provide a poor basis of comparison, are the only available information that gives some indication of the magnitude of the risk.

OSHA concluded in post-1980 rulemakings that it was the intent of Congress to reduce risks of average magnitude and the Supreme Court indicated that a reasonable person "might well consider a risk of 1/1000 [100/100,000] significant and take steps to decrease or eliminate it" (*I.U.D. v. A.P.I.*, 448 U.S. 655). The cancer risk posed by formaldehyde is in addition to risks of accidental injury and death which otherwise exist in the industries where workers are exposed to formaldehyde. The cancer risk is in addition to the risk of other, non-life-threatening but potentially materially impairing risks to the worker's health posed by formaldehyde's irritating and sensitizing properties.

In determining what constitutes a significant risk for formaldehyde, OSHA also examined the risks posed by other standards recently promulgated by the Agency, for example, benzene, asbestos, and ethylene oxide. The risk of formaldehyde exposure posed by the old PEL was somewhat lower than for these other standards so the fact that the relative reduction in the formaldehyde standard is only 3-fold is not unreasonable.

Although OSHA has considerable confidence in the biological information used to support the findings of formaldehyde's carcinogenicity, the quantitative risk estimates for formaldehyde are somewhat less certain than risk estimates that OSHA has performed for toxic substances where there has been a wealth of human data available. Nonetheless, plausible

estimates of risk for formaldehyde provide a basis for concluding that the magnitude of the cancer risk is significant if workers are exposed to 3 ppm for a working lifetime.

Estimates of risk at exposures of 1 ppm have greater uncertainty than those made at 3 ppm. The 1 ppm exposures are outside of the applied dose in the CIIT study. The extrapolation to the nonlinear data result in large differences between the different approaches and mathematical models used. Plausible estimates of risk at 1 ppm vary by a factor of over 400; risk estimates at 3 ppm vary less, by a factor of 42. OSHA does not have experience in determining what constitutes insignificant risk but believes that figures of 0.6/100,000 (*i.e.* 6 in a million) predicted by the lower end of the range may be approaching a level that can be viewed as safe in the context of the workplace environment. A risk assessment provides estimates of risk to individuals; because of biological variability some individuals are at greater risk than predicted; some are at lesser risk. OSHA's findings are supported by the observations of the risk that were discussed in the previous paragraphs concerning the reasonableness of the risk assessment.

The new PEL substantially reduces the significant risk incurred by exposures at 3 ppm. The dose-response relationship indicates that reducing exposure reduces risk. The 5-stage UCL estimates of risk indicate that the new standard would reduce the risk by a substantial 67 percent. MLE estimates are based on dose-response curves that show a steeper slope, and they predict even greater reductions in risk. For example, the Clement Associates MLE estimate indicates a reduction of 96 percent. OSHA concludes on this basis that the new PEL substantially reduces the risk of cancer to workers.

OSHA believes that the presence of the additional provisions in the formaldehyde standard act together to reduce the risk of occupational exposure to formaldehyde to levels substantially less than that predicated on the basis of the 1 ppm TWA alone. Provisions, such as annual training, medical surveillance, hazard communication, emergency plans, personal protective equipment, housekeeping, and exposure monitoring, work together in an inextricable manner to provide additional protection to workers both from cancer and from other toxic effects.

The standard being revised also permitted worker exposure to levels as high as 10 ppm for as much as 30 minutes in the workshift. OSHA's risk estimates derived from animal data are based on uniform delivery of

formaldehyde throughout the exposure period, and they do not account for peaks in exposure. Humans would be at some undefined higher risk than the assessment based on animal data would indicate if they received peak exposures since there are known dose-rate effects for formaldehyde. Reducing the 10 ppm peak to a STEL of 2 ppm will also greatly reduce this extra risk of cancer in workers. Thus, OSHA concludes that a PEL of 1 ppm with the additional provisions of this standard will eliminate the significant risk of cancer.

There is evidence to indicate that employee exposure is substantially below the existing PELs. Industries that testified before OSHA indicated that they and many other companies comply with the ACGIH threshold limit values of 1 ppm as an 8-hour average and 2 ppm as a 15-minute STEL. Certain state-plan states also have a lower standard for formaldehyde than the national program at OSHA. Consequently, few workers are currently exposed to formaldehyde at 3 ppm as an 8-hour TWA or 10 ppm as a peak. Indeed, industry groups have described such exposures as "intolerable" [Exs. 8; 80-79]. OSHA believes that most employees are not confronted by risks as high as those calculated by OSHA. Few workers are exposed to 3 ppm. However, the existing standard permits exposures to dangerous levels, and some workers remain exposed at these levels. Thus, OSHA has authority to revise the standard.

Information reported in the Health Effects section of this preamble clearly indicates that there are dose-rate effects for cytotoxicity and cell proliferation, in the short term (*e.g.* 36 ppm-hr) [Exs. 42-115; 70-23], in subchronic studies, and when tissue changes in chronic studies conducted with 6-hr exposures are compared with those in animals from continuous 24-hr exposure studies. To the extent that cytotoxicity parallels cancer incidence by acting as a cancer promoter, these studies indicate that a ceiling must be placed on the amount of exposure a worker receives over brief intervals to permit tissue recovery and prevent placing the worker at higher risk of cancer. As Dr. Robert Squire, a pathologist formerly with the NCI animal bioassay program who testified for the FI, stated, "short term excursions at higher levels would have little effect on tumor promotion if there were time for recovery between exposure peaks since one would expect reversal of the acute effects" [Tr. May 12, 1986, p. 81]. Thus, in theory, by placing limitations on the amount of short-term, high dose exposure a worker receives, cancer risk can be lowered, and perhaps even

eliminated. OSHA, however, does not have quantitative evidence relating cytotoxicity to cancer rates and does not have any information on chronic bioassays conducted with intermittent peak exposures. Thus, no attempt could be made to determine how dose rate would influence extra risk of cancer. The 2 ppm STEL should serve to further lower the risk of cancer. OSHA notes, however, that the selection of this figure was based primarily on expert testimony and evidence that irritant effects are intolerably severe above this level.

Significance of Sensory Irritation: Precise, mathematical analyses for material impairments based on skin diseases and disorders and on sensory irritation and sensitization were not possible despite OSHA's repeated efforts to collect, develop, and analyze quantitative data on these effects.

Assessments of sensory irritation in OSHA's record were based on the investigator's ability to elicit a meaningful description of a subject's degree of irritation. These studies showed a dose-rate effect. There was no information available which permitted OSHA to relate these irritation scores directly to morbidity, productivity data, or lost workdays [Ex. 86-10, Att. E, p. 4].

For these reasons, the Agency relied upon abundant, essentially unanimous and uncontroverted expert opinion and information in the record to determine workplace conditions that are felt to cause a significant risk of irritation and sensitization. The significance of these risks and their widespread occurrence in the workplace are confirmed by universally accepted principles of public health and substantiated by numerous studies in the record, particularly from NIOSH's program for detection of health hazards in the workplace.

In determining the degree of exposure that would result in a significant risk from sensory irritation, OSHA was guided, in part, by its deliberations in regulating occupational exposure to lead. For lead, certain sub-clinical effects are manifest in workers before clinical evidence clearly demonstrating that a material impairment has occurred. When these impairments are detected at the sub-clinical stage, they are still reversible, and the material impairment can be prevented. Subclinical effects indicated that the worker had been placed at significant risk of future material impairment unless the exposure was stopped.

While the connection between sensory irritation and increased cancer risk from formaldehyde exposure is more obscure than the relation between

subclinical effects and material impairments for lead, when the sensory nerves react, it is because they are receiving a direct exposure to formaldehyde. In such circumstances, the entire respiratory system may be receiving exposure, indicating an increased risk of cancer.

Numerous studies of volunteers and workers demonstrate that as concentration increases, both the number of biological effects and the severity of each irritant effect increase. First, in persons who are at rest, eye irritation develops. Next, the irritation spreads to the nose and then the throat. Strenuous exercise, which causes an increase in air intake into the respiratory system, may reverse the order of eye and upper airways irritation [Ex. 138-R]. As exposure increases, irritation spreads deeper into the respiratory system causing constriction of the bronchial passages. At concentrations approaching 50 ppm, which could occur in some foreseeable accidents, chemical pneumonitis may develop.

At levels permitted by the ceiling and peak exposure limits presently being revised, sensory irritation in humans is clearly a material impairment of health, causing burning and tearing of the eyes, severe irritation of the nose and throat, and even some effects lower in the respiratory system. Even at the TWA concentration of 3 ppm, nearly 100 percent of the workforce would experience some irritation of the eyes, nose, and throat. Twenty percent would experience moderate to strong irritation with great discomfort. Over 30 percent would experience mild to moderate irritation and discomfort (see risk assessment section). Such responses would impair a worker's ability to function on the job; all information on OSHA's record supports a determination that effects seen at 3 ppm are of sufficient severity that they represent material impairment of health to a substantial number of workers even though they are acute and recovery occurs rapidly when the worker is removed from the worksite exposure.

To make a determination of the concentration of formaldehyde that must not be exceeded to prevent material impairment of health or functional capacity from sensory irritation, OSHA could not rely on precise, quantitative analysis because of the nature of the hazard. Assessment of the risk of sensory irritation is based necessarily upon imperfect, often subjective, data, and the Agency relied primarily on the virtually unanimous and uncontroverted expert testimony and opinion in the

record to determine the level of exposure needed to prevent the appearance of substantial effects in a significant number of workers.

Sensory irritation has been experienced at levels as low as 0.05 ppm [Ex. 73-144], but effects at levels below 0.1 ppm appear so mild in all reported individuals that acute effects at such exposures would not constitute a significant risk of material impairment of health. At 0.1 ppm, no material impairment of health from irritation or sensitization has been reported (see for example, Ex. 86-10, Att. A. p. 16 and Att. E, p. 27), and this level is presumed, on the basis of the presently existing best available evidence, to be within the no-observed-effect-level (NOEL) for formaldehyde for noncarcinogenic effects related to airborne exposure.

At levels between 0.1 and 0.5 ppm, many members of the general population experience sensory irritation, but this is only slight in persons not specifically sensitized to formaldehyde. OSHA included provisions for medical evaluation for persons who clearly demonstrate symptoms that might be caused or aggravated by formaldehyde; most of these persons will be "hypersensitive." Workers exposed at levels between 0.1 and 0.5 ppm will also be covered under worker right-to-know provisions and receive training on the hazards of formaldehyde. Consequently, it may be possible for some workers to continue working with formaldehyde even though they appear to be "hypersensitive."

At levels greater than 0.5 ppm but at or below 1 ppm, a substantial number of nonsensitized workers will have some sensory irritation from formaldehyde. In a few cases, the irritation will be sufficiently severe to interfere with job performance and possibly even endanger others. Other persons will have preexisting conditions which will be aggravated by exposure to formaldehyde. Because investigators have measured subjective symptoms of irritation by relying on descriptions from the exposed subject, an individual's perceptions of "severity" can influence test results. Thus, a wide range of results have been reported: this makes precise quantification of the various degrees of sensory irritation at exact exposure levels impossible. However, all reports in workers and in volunteer subjects show a consistent trend suggesting that lowering exposure will lower severity of symptoms, a view also held by expert witnesses and industry physicians who have been responsible for health care for formaldehyde workers.

Because effects are more severe at levels between 0.5 and 1 ppm than at levels between 0.1 and 0.5 ppm, OSHA has required annual review of each employee's medical status and annual training of these employees to assure that they can recognize signs and symptoms of formaldehyde exposure. These provisions, along with the requirement that employers should supply respirators to those who feel that they must wear them to relieve formaldehyde-induced symptoms, will reduce the risk of sensory irritation substantially below that which would otherwise be expected to occur at levels between 0.5 and 1 ppm.

At levels greater than 1 ppm, evidence available to OSHA consistently shows that nearly all workers experience some sensory irritation from formaldehyde. Without a limit on exposures of short duration, these levels could rise as high as 32 ppm for a 15 minute exposure before the 1 ppm TWA would be exceeded. Such levels would cause severe lacrimation, clearly a significant impairment of functional capacity, since it would impeded the worker's ability to escape from the toxic environment. Workers would also experience lower respiratory tract irritation, indicating that substantial amounts of formaldehyde are reaching the lung. These acute effects clearly represent significant material impairments of health. Partly for this reason, OSHA is promulgating a STEL of 2 ppm. This 2 ppm STEL will greatly reduce the risk of serious injury of workers from acute exposure to formaldehyde that would otherwise be possible.

Even when concentrations are uniformly spread over an 8-hour period, the severity of irritant effects that can occur when exposures exceed 1 ppm is sufficient to represent material impairment of health. The NAS report [Ex. 42-87] indicates that 20 percent of the population exposed at 1.5 to 3 ppm would have signs and symptoms ranging from moderate irritation with discomfort to strong irritation with great discomfort. Many of these persons would feel that their health was impaired and their productivity would suffer since their presence at work would make them feel as if they were suffering from a "cold" or the "flu." With an incidence probably approaching 1 in 10 workers, and possibly as great as 1 in 5 workers, OSHA considers that despite the reversibility of the effects, such exposures pose a significant risk of material health impairment.

OSHA has estimated that at least 10 percent of the workers exposed above the action level or the STEL will

experience a reduction in adverse respiratory symptoms based on the reduced exposure levels that will result following implementation of the standard (see OSHA's Regulatory Impact Analysis). Some hypersensitive persons will also be protected by the standard, giving an even greater number of persons whose symptoms will be alleviated. OSHA finds that this is a substantial reduction in risk.

Significance of Pulmonary Effects: Formaldehyde is capable of inducing occupational asthma and of causing adverse responses such as bronchitis in hypersusceptible persons. A NIOSH study indicated that persons with asthmatic symptoms could often relate the onset of these symptoms to a specific short-term high exposure or emergency situation. At concentrations exceeding 1 ppm, workers have shown fairly consistent, but moderate acute shifts in pulmonary function across the workshift, although volunteers, even if they were histamine reactive, have generally remained unresponsive when exposures of short duration were in the 1 ppm range. Concentrations at or above 3 ppm may be needed to induce progressive loss of pulmonary function and to provide a response in histamine-sensitive individuals not specifically reactive to formaldehyde. Progressive loss of pulmonary function and formaldehyde-specific sensitization clearly represent material impairments of health; this is aggravated by the likelihood that a person specifically sensitive to formaldehyde may be unable to continue working with any amount of airborne formaldehyde.

Because of limitations imposed by the available data base, the suspected underreporting of cases [Ex. 104-E1], and the lack of data on incidence rates of the disease at 3 and 1 ppm, it is not possible to quantify the reduction in risk of asthma from formaldehyde exposure. It is probable that peak exposures of 10 ppm have induced cases of asthma in workers (see Exs. 42-100 42-106); such exposures definitely aggravated conditions in those already sensitized [Exs. 42-62; 42-63; 42-66].

Full compliance with the new standard for occupational exposure to formaldehyde, in particular with provisions for the STEL, the TWA, and the emergency evacuation and medical surveillance procedures should reduce the number of new cases of pulmonary sensitization. Compliance with all provisions of the standard also should permit some individuals who are "intrinsically susceptible" to work with formaldehyde without developing

adverse reactions, particularly if exposure is below the action level.

Significance of Dermal Exposure: For skin diseases and disorders, data available in the formaldehyde record were sufficient to roughly quantify the risks posed to workers under existing workplace conditions.

Formaldehyde causes irritation and sensitization of the skin. Direct chemically-induced irritation can occur from formaldehyde solutions greater than 5 percent [Ex. 69-23 C6], and possibly from solutions as low as 2 percent, the reason that patch-testing of formalin is now performed with 1 percent solution [Ex. 92]. Concentrated formalin solution also cause sensitization: 72 percent of a group exposed to 5 percent formalin and challenged with 1 percent formalin were sensitized to formaldehyde [Ex. 42-75]. The risk of formaldehyde-induced dermatitis appears to vary widely depending on work practices, availability of protective equipment, the formaldehyde-bearing material being handled, and the nature of the work.

Irritation from and sensitization to textiles is well known. Not all of the cases of textile dermatitis are caused by formaldehyde, since other irritating and sensitizing chemicals are also present. However, protection provided as a result of the formaldehyde standard will alleviate the effects of the other chemicals as well. At concentrations above 1 percent, and possibly below [Ex. 42-27], formaldehyde solutions can induce dermal sensitization in persons who have contact with these materials.

While irritation of the skin can be transient, and does not necessarily result in lost worktime, sensitization is invariably a serious problem. Once sensitized, and employee will probably continue to react to small concentrations of formaldehyde for years. Dermal sensitization can severely limit a worker's ability to pursue employment and disrupt the worker's personal life (because formaldehyde use in small amounts is so pervasive in many consumer products, from shampoos and cosmetics to rugs), so that sensitization is clearly a serious and material impairment of health.

Skin diseases and disorders have traditionally been the leading cause of occupational illness reported to the Bureau of Labor Statistics. While dermatitis is not a life-threatening disease, it results in loss of productivity and it often results in medical expenses and lost worktime. OSHA's Regulatory Impact Analysis estimates that the medical costs associated with a typical case of allergic dermatitis are \$407; in

the apparel industry an average of 30 workdays were lost in 1985 for each case of skin disease reported to the Bureau of Labor Statistics.

The incidence rates of reportable occupational illness related to skin disease or disorders for 1985 was 10.9/10,000 full-time workers in textile finishing (except wool), SIC 2260, and 4.4/10,000 in the apparel industry, SIC 23. These rates are substantially above low risk industries, such as finance, insurance, and real estate, where the rates is 1.0/10,000 full-time workers.

OSHA has no estimate on the incidence rate of formaldehyde-induced skin disease in the workplace. However, about 4 percent of all patients tested in allergy clinics were found to be sensitized [Exs. 42-75; 42-93]. If the percent of employees who would become sensitized to formaldehyde without the use of personal protection is similar to the incidence seen in allergy clinics, then provision of protective clothing to 269,700 employees exposed to formaldehyde would prevent 10,790 cases of allergic dermatitis annually. Moreover, numerous cases of non-allergic skin irritation, which would not have consequences as serious as allergic dermatitis, would also be prevented (see OSHA's Regulatory Impact Analysis). OSHA believes that the risk of skin diseases and disorders among workers who come into contact with formaldehyde solutions and formaldehyde-bearing solids is significant and that this risk will be substantially reduced by the new standard for formaldehyde.

In a few cases, information was sufficient to quantify the risks of skin diseases and disorders in specific industry sectors. These cases could be used to determine the likely benefits of full compliance with the revised formaldehyde standard since improved work practices and housekeeping along with the use of adequate protective clothing and equipment should virtually eliminate skin diseases and disorders.

Available literature on dermatitis (both irritation and sensitization) was generally derived from "problem areas" where NIOSH HHEs have been requested or where investigators were examining known hazards. The information available is generally on skin disease of a serious nature and does not distinguish between irritation and sensitization. There are five studies of textile dermatitis [Exs. 77-11; 78-84; 85-20; 85-23; 85-24]. Incidences ranged from 3 to 58 percent of those administered questionnaires with some

correlation between incidence rates, the amount of releaseable formaldehyde in the fabric, and airborne concentrations of formaldehyde. (Heat and humidity also influence release of formaldehyde, as does the age of the cloth and whether or not it has been washed.) Twenty-six percent of 874 workers were affected. Airborne levels in all but one case were below 0.5 ppm indicating a need to provide protection from dermal contact regardless of the airborne level of formaldehyde.

There are also reports of adverse health effects in persons who handled tissue-preserving solutions [Exs. 42-101; 42-123; 73-88D; 78-53]. Dermatitis, either irritant or sensitizing, was found in 28 to 37 percent of these workers. (The effects described were more severe than those generally seen in the apparel workers, even though most wore gloves some of the time.) A total of 47 cases in 140 individuals was reported, for an overall incidence rate of 33.6 percent, well above figures reported in the overall occupational setting and well above the incidences observed in dermatology clinics [Ex. 42-75]. Available literature indicates that the incidence of asthma and bronchitis, as well as the incidence of dermal irritation and sensitization, may be quite high in this group (see Health Effects section).

Summary of the Significance of the Risk: OSHA has determined that the existing standard for formaldehyde poses significant risk to employees of cancer, sensory irritation, dermatitis, and asthma. Full compliance with all of the provisions of the revised standard (1 ppm TWA, 2 ppm STEL, and ancillary provisions) will substantially reduce these risks to a level that can be viewed as safe for the worker. These findings have been made using the approach which OSHA has used in setting other standards for toxic substances since the Benzene decision and are consistent with the formaldehyde rulemaking record.

VIII. Summary of Regulatory Impact and Regulatory Flexibility Analysis

Executive Order 12291 (46 FR 13197, February 19, 1981) requires that a regulatory analysis be conducted for any rule having major economic consequences on the national economy, individual industries, geographical regions, or levels of government. In addition, the Regulatory Flexibility Act of 1980, 5 U.S.C. 601 et seq., requires OSHA to determine whether a regulation will have a significant impact

on a substantial number of small entities.

Consistent with these requirements, OSHA has prepared a Regulatory Impact and Regulatory Flexibility Analysis (RIA) for the formaldehyde standard. This analysis includes a profile of the industries that are covered by the standard, an estimate of the number of exposed workers, a review of the nonregulatory alternatives, and assessments of the technological feasibility, costs, benefits, and overall economic impacts of the final standard. This RIA is available at the OSHA Docket Office.

Based upon an analysis of the record, OSHA has determined that the industries affected by the revised standard can be grouped into three classes, according to the potential exposure levels. Tier One, which covers approximately 36,000 affected establishments and approximately 412,000 exposed workers, consists of the industries where some firms have workers who are currently exposed above either the 1 ppm PEL or 2 ppm STEL. This group is comprised of foundries, laboratories, funeral homes, and industry sectors engaged in the manufacture of: (1) Hardwood plywood, (2) particleboard, (3) fiberboard, (4) furniture, and (5) formaldehyde resins. Tier Two, which includes approximately 29,000 affected establishments and approximately 1.1 million exposed workers, consists of the industries where some firms have workers who are currently exposed between the 0.5 ppm action level and the 1 ppm PEL and where no firms have employees exposed above either the 1 ppm PEL or 2 ppm STEL. This group is comprised of textile finishing and industry sectors engaged in the manufacture of: (1) Apparel, (2) formaldehyde, and (3) plastic molding. Tier Three consists of 24 industries where some workers are currently exposed above 0.1 ppm and where no employees are exposed above the 0.5 ppm action level. This group covers approximately 47,000 establishments and approximately 676,000 workers. Table 5 presents OSHA's estimate of the number of affected establishments and employees for each of the affected industry sectors. Establishments are grouped by the highest exposure found within the establishment.

Based on the rulemaking record, OSHA has determined that compliance with the revised standard is technologically feasible. Exposures in

the Tier One industries can be reduced to below the PEL and STEL through the increased use of ventilation (either local or general), and the substitution of low emitting urea formaldehyde resins (LEUF). No industry representatives contended that such controls could not achieve these limits. Personal protective equipment (e.g., gloves, goggles, respirators, etc.), monitoring badges, and hygiene equipment (e.g., eye wash and emergency shower) are also readily available. Medical resources will not be a problem because the medical surveillance questionnaire, of which an example is provided in nonmandatory Appendix D to the standard, may be administered under the supervision of, and not necessarily by, a physician. Also, the medical exams, when required, consist of standard tests. Finally, the requirements of several provisions (e.g., recordkeeping, the development of an emergency plan, and employee training) can be met using in-house personnel.

OSHA estimates that the annual cost of the revised standard will be approximately \$64.2 million. Medical surveillance (\$12.9 million), and the installation, maintenance and operation of the required engineering controls in Tier One (\$27.6 million) are the two most expensive provisions, accounting for 20 percent and 43 percent of total annual costs, respectively. Table 6 provides a breakdown of industry compliance costs by exposure level of individual establishments.

OSHA has determined that compliance with the revised standard is economically feasible for firms in each of the industry sectors based upon an industry-specific analysis of revenue and profit ratios. Table 7 displays total annualized compliance costs for each industry as a percentage of annual industry sales and profits. The annual compliance costs are less than one-half of one percent of revenues in all sectors except for the fiberboard sector, where this ratio is 1.65 percent. Impacts of this magnitude will not adversely impact the viability of most firms in these industries. Where data allowed, OSHA also examined profit levels of the industries affected by the standard and determined that in all but a few of the wood product sectors, costs would not exceed 3 percent of profits. For those industries, improved growth spurred by the reduced value of the U.S. dollar will permit the industry to pass through some of the costs of compliance to the purchasers of these products.

TABLE 5.—NUMBER OF AFFECTED ESTABLISHMENTS AND EMPLOYEES

SIC and industry	Establishments					Employees				
	Total	Above 1 PPM	Between 0.5-1 PPM	Between 0.1-0.5 PPM	Total affected	Production Employees	Above 1 PPM	Between 0.5-1 PPM	Between 0.1-0.5 PPM	Total exposed
Tier One With Exposures From 0.1 to Above 1.0 ppm)										
2435—Hardwood plywood.....	306	40	66	94	200	16,000	455	1,574	8,699	10,728
2492—Particleboard.....	54	14	16	16	46	6,100	301	1,440	2,836	4,577
2499—Fiberboard.....	14	9	5	0	14	1,537	230	588	335	1,153
25—Furniture.....	10,003	184	2,646	2,645	5,474	482,014	1,031	23,223	235,095	259,349
2821—Resins.....	440	35	31	31	97	32,800	385	980	8,335	9,700
332, 336—Foundries.....	4,004	1,047	1,435	520	3,002	171,800	4,509	12,169	43,322	60,000
806, 807—Laboratories ²	14,000	2,137	1,861	8,167	12,165	42,000	6,269	5,951	24,441	36,661
7261—Funeral services ³	15,128	0	0	15,000	15,000	76,026	0	0	30,000	30,000
Subtotal.....	43,949	3,466	6,060	26,473	35,998	828,277	13,180	45,925	353,063	412,168
Tier Two (With Exposures From 0.1-1.0 ppm)										
226—Textile finishing.....	723	0	685	0	684	42,900	0	19,125	10,298	29,423
23—Apparel.....	24,391	0	5,737	17,211	22,948	960,000	0	117,663	823,637	941,300
2869—Formaldehyde production.....	688	0	16	33	49	59,500	0	480	3,401	3,881
3079—Plastic molding.....	11,653	0	1,000	4,000	5,000	450,000	0	10,000	90,000	100,000
Subtotal.....	37,455	0	7,438	21,244	28,682	1,512,400	0	147,268	927,336	1,074,603
Total of first and second tier industries.....	81,404	3,466	13,498	47,717	64,680	2,340,677	13,180	193,193	1,280,399	1,486,771
Tier three (With Exposures from 0.1-0.5 ppm)										
2436—Softwood plywood.....	250	0	0	250	250	31,100	0	0	31,100	31,100
2611—Pulp mills.....	43	0	0	43	43	12,800	0	0	12,800	12,800
2621—Paper mills.....	299	0	0	299	299	100,100	0	0	100,100	100,100
2631—Paperboard mills.....	222	0	0	222	222	43,000	0	0	43,000	43,000
2642—Envelopes.....	296	0	0	296	296	19,000	0	0	19,000	19,000
2653—Corrugated and solid fiber boxes.....	1,491	0	0	1,491	1,491	67,400	0	0	67,400	67,400
2865—Cyclic crudes, cyclic intermediates, dyes.....	189	0	0	189	189	16,000	0	0	16,000	16,000
2851—Paints, pigments.....	1,441	0	0	1,441	1,441	27,600	0	0	27,600	27,600
2873—Nitrogenous fertilizers.....	152	0	0	152	152	6,300	0	0	6,300	6,300
2879—Agricultural chemicals, NEC.....	330	0	0	330	330	9,700	0	0	9,700	9,700
2891—Adhesives and sealants.....	683	0	0	683	683	10,900	0	0	10,900	10,900
2899—Chemicals and chemical preparations, NEC.....	1,439	0	0	1,439	1,439	23,100	0	0	23,100	23,100
3291—Abrasive products.....	374	0	0	374	374	17,000	0	0	17,000	17,000
3293—Gaskets, packaging and sealing devices.....	474	0	0	474	474	21,800	0	0	21,800	21,800
3296—Mineral wool insulation.....	179	0	0	179	179	15,500	0	0	15,500	15,500
3634—Electric housewares and fans.....	263	0	0	263	263	29,300	0	0	29,300	29,300
3643—Current-carrying wiring devices.....	415	0	0	415	415	31,900	0	0	31,900	31,900
3644—Noncurrent-carrying wiring devices.....	226	0	0	226	226	18,100	0	0	18,100	18,100
3694—Electrical equip. for int. comb. engines.....	433	0	0	433	433	32,300	0	0	32,300	32,300
3792—Mobile home manufacturing.....	1,655	0	0	1,655	1,655	11,200	0	0	11,200	11,200
7395—Photofinishing labs.....	3,589	0	0	3,589	3,589	71,742	0	0	71,742	71,742
806—Hemodialysis.....	10,500	0	0	10,500	10,500	31,500	0	0	31,500	31,500
822—Biology instruction.....	22,575	0	0	22,575	22,575	28,950	0	0	28,950	28,950
822—Veterinary anatomy.....	19	0	0	19	19	38	0	0	38	38
Subtotal.....	47,537	0	0	47,537	47,537	676,330	0	0	676,330	676,330
Total.....	128,941	3,466	13,498	95,254	112,217	3,017,007	13,180	193,193	1,956,729	2,163,101

¹ Figures represent total employees.² Pathology, histology and gross anatomy labs.³ Some establishments exceed STEL.

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

TABLE 6.—COMPLIANCE COSTS BY INDUSTRY AND PROVISION

Industry	Engineering controls		Emergency plan	Hygiene facilities	Exposure monitoring		Respirators	Protective clothing	Training	Record-keeping	House-keeping	Medical surveillance	Total industry annualized costs
	PEL	STEL			Recurring	Initial							
With Exposures Above 1 PPM													
Hardwood plywood	541,397	0	903	0	5,369	708	0	0	5,666	891	739	12,296	567,969
Particleboard	3,267,672	0	427	0	3,552	468	11,200	0	3,743	599	259	7,436	3,295,355
Fiberboard	3,951,501	0	133	0	2,714	358	7,200	0	2,860	457	166	4,735	3,970,125
Furniture	3,515,854	0	3,349	0	12,166	1,605	0	0	16,371	2,040	3,398	24,764	3,579,546
Resins	343,869	57,878	890	0	4,543	599	0	1,984	7,902	695	646	3,644	422,652
Foundries	9,961,737	0	23,757	0	53,206	8,148	0	0	103,656	8,393	19,334	115,816	10,294,047
Laboratories	5,510,053	0	24,706	0	126,083	16,630	0	323,135	139,471	11,744	19,731	162,054	6,333,607
Funeral services	0	445,759	0	0	0	0	0	0	0	0	0	0	445,759
Subtotal	27,092,083	503,638	54,166	0	207,633	28,516	18,400	325,120	279,669	24,819	44,272	330,745	28,909,060
With Exposures Between 0.5 and 1 PPM													
Hardwood plywood	0	0	1,491	0	18,573	2,450	0	0	18,354	3,083	1,219	42,537	87,707
Particleboard	0	0	488	0	16,992	2,241	0	0	17,907	2,864	295	35,573	76,361
Fiberboard	0	0	74	0	6,938	915	0	0	7,312	1,170	92	12,105	28,606
Furniture	0	0	48,156	0	274,031	36,144	0	0	329,796	45,956	48,861	557,799	1,340,743
Resins	0	0	788	0	11,564	1,525	0	5,051	19,149	1,769	572	9,276	49,696
Foundries	0	0	32,561	0	143,594	18,940	0	0	243,591	22,651	26,498	312,567	800,403
Laboratories	0	0	21,515	0	109,799	14,482	0	306,744	128,039	11,148	17,182	153,833	762,743
Funeral services	0	0	0	0	0	0	0	0	0	0	0	0	0
Textile finishing	N/R	N/R	14,596	55,740	225,675	29,766	N/R	922,733	233,987	37,065	12,649	511,460	2,043,671
Apparel	N/R	N/R	0	0	1,388,418	183,131	N/R	247,091	1,247,916	240,054	0	3,312,552	6,619,162
Formaldehyde production	N/R	N/R	370	0	5,664	747	N/R	317	7,187	1,087	295	13,196	28,864
Plastic molding	N/R	N/R	19,064	40,686	118,000	15,564	N/R	48,595	150,868	20,095	18,466	138,650	569,988
Subtotal	0	0	139,104	96,427	2,319,249	305,906	0	1,530,531	2,404,107	386,942	126,131	5,099,548	12,407,944
With Exposures Between 0.1 and 0.5 PPM													
Hardwood plywood	0	0	2,123	0	0	8,349	0	0	0	21,010	1,736	41,946	75,164
Particleboard	0	0	488	0	0	2,207	0	0	0	5,641	295	10,136	18,767
Fiberboard	0	0	0	0	0	275	0	0	0	666	0	998	1,939
Furniture	0	0	48,138	0	0	182,952	0	0	0	465,226	48,842	816,984	1,562,142
Resins	0	0	788	0	0	6,486	0	42,963	0	15,046	572	11,415	77,271
Foundries	0	0	11,799	0	0	33,713	0	0	0	80,639	9,602	160,993	296,747
Laboratories	0	0	94,420	0	0	31,778	0	1,259,810	0	45,785	75,405	91,409	1,598,607
Funeral services	0	0	176,295	1,220,590	0	58,365	0	286,348	0	56,199	0	112,200	1,909,998
Textile finishing	N/R	N/R	0	0	0	8,456	N/R	24,843	0	19,958	0	39,845	93,102
Apparel	N/R	N/R	0	0	0	640,956	N/R	1,729,638	0	1,680,379	0	3,354,838	7,405,812
Formaldehyde production	N/R	N/R	764	0	0	2,647	N/R	2,243	0	7,703	609	13,527	27,493
Plastic molding	N/R	N/R	76,255	162,745	0	70,038	N/R	437,354	0	180,859	73,863	180,540	1,181,655
Softwood plywood	N/R	N/R	7,481	20,343	N/R	4,389	N/R	13,458	N/R	5,523	4,616	110,262	166,073
Pulp mills	N/R	N/R	1,488	3,499	N/R	2,006	N/R	6,150	N/R	2,315	794	46,222	62,474
Paper mills	N/R	N/R	10,784	24,330	N/R	16,046	N/R	49,203	N/R	18,523	5,521	369,813	494,221
Paperboard mills	N/R	N/R	7,492	18,065	N/R	6,948	N/R	21,306	N/R	8,021	4,099	160,138	226,070
Envelopes	N/R	N/R	7,808	24,086	N/R	3,112	N/R	9,541	N/R	3,813	5,466	76,130	129,956
Corrugated and solid fiber boxes	N/R	N/R	37,765	121,327	N/R	12,137	N/R	37,217	N/R	14,476	27,533	289,001	539,455
Cyclic crudes, dyes and pigments	N/R	N/R	5,107	0	N/R	3,436	N/R	6,513	N/R	395	3,490	7,882	26,823
Paints, pigments	N/R	N/R	27,361	117,258	N/R	6,693	N/R	41,043	N/R	8,055	26,609	160,820	387,839
Nitrogenous fertilizers	N/R	N/R	3,421	0	N/R	638	N/R	0	N/R	379	2,807	7,562	14,807
Agricultural chemicals	N/R	N/R	5,804	0	N/R	1,074	N/R	0	N/R	637	6,094	12,727	26,336
Adhesives and sealants	N/R	N/R	11,811	27,789	N/R	1,909	N/R	11,708	N/R	1,138	12,612	22,729	89,697
Chemicals and chemical preparations	N/R	N/R	23,729	0	N/R	5,335	N/R	32,718	N/R	6,363	26,572	0	94,717
Abrasive products	N/R	N/R	7,650	0	N/R	3,338	N/R	0	N/R	3,945	6,906	78,757	100,596
Gaskets, packaging and sealing devices	N/R	N/R	10,098	38,571	N/R	3,097	N/R	9,487	N/R	3,660	8,753	73,073	146,749
Mineral wool insulation	N/R	N/R	4,252	14,566	N/R	2,499	N/R	7,664	N/R	2,953	3,305	58,965	94,205
Electric housewares and fans	N/R	N/R	6,207	21,401	N/R	4,876	N/R	14,950	N/R	5,922	4,857	118,224	176,436
Current-carrying wiring devices	N/R	N/R	9,560	33,770	N/R	5,639	N/R	17,291	N/R	6,787	7,663	135,500	216,210
Noncurrent-carrying wiring devices	N/R	N/R	5,392	18,390	N/R	3,323	N/R	10,190	N/R	4,000	4,173	79,856	125,325
Electrical equipment for combustion engines	N/R	N/R	9,022	35,234	N/R	5,442	N/R	16,687	N/R	6,372	7,996	127,206	207,959
Mobile homes manufacturing	N/R	N/R	27,508	0	N/R	11,424	N/R	0	N/R	15,188	30,561	303,215	387,896
Photofinishing labs	N/R	N/R	51,780	219,035	N/R	11,159	N/R	513,279	N/R	13,432	66,274	268,158	1,143,116
Hemodialysis	N/R	N/R	121,392	854,413	N/R	40,856	N/R	300,666	N/R	1,475	193,891	29,453	1,542,145
Biology instructors	N/R	N/R	623,923	918,494	N/R	87,840	N/R	303,975	N/R	5,423	208,433	108,273	2,256,361
Veterinary anatomist	N/R	N/R	525	773	N/R	74	N/R	399	N/R	71	351	142	2,335
Subtotal	0	0	1,438,431	3,894,680	0	1,289,512	0	5,206,654	0	2,717,977	880,303	7,478,941	22,906,499
Total	27,092,083	503,638	1,631,682	3,991,107	2,526,882	1,620,769	18,400	7,062,304	2,682,734	3,125,765	1,050,687	12,901,301	64,207,351

Note.—Numbers may not add precisely due to rounding.

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE 7.—COMPLIANCE COSTS AS A PERCENTAGE OF REVENUES AND PROFITS

SIC and industry	Annualized costs (millions of dollars)	Costs as percent of revenues	Costs as percent of profits
2435—Hardwood plywood	0.717	0.047	4.03
2492—Particleboard	3.390	0.346	6.92
2499—Medium density fiberboard	4.001	1.650	NA
25—Furniture	6.482	0.038	1.48
2821—Resins	0.549	0.003	0.07
332, 336—Foundries	11.390	0.068	2.27
806, 807—Laboratories	8.695	0.008	NA
7261—Funeral services	2.356	0.048	0.50
226—Textile finishing	2.136	0.038	0.22
23—Apparel	14.025	0.025	1.37
2869—Formaldehyde production	0.056	0.000	0.00
3079—Plastic molding	1.752	0.004	NA
2436—Softwood plywood	0.166	0.002	0.00
2611—Pulp mills	0.062	0.002	0.04
2621—Paper mills	0.494	0.002	0.04
2631—Paperboard mills	0.226	0.002	0.05
2642—Envelopes	0.130	0.006	0.16
2653—Corrugated and solid fiber boxes	0.539	0.004	0.10
2865—Cyclic crudes, dyes and pigments	0.027	0.000	0.01
2851—Paints, pigments	0.388	0.003	0.09
2873—Nitrogenous fertilizers	0.015	0.000	0.03
2879—Agricultural chemicals	0.026	0.001	NA
2891—Adhesives and sealants	0.090	0.002	0.06
2899—Chemicals and chemical preparations	0.095	0.001	NA
3291—Abrasive products	0.101	0.003	NA
3293—Gaskets, packaging and sealing devices	0.147	0.007	NA
3296—Mineral wool insulation	0.094	0.003	NA
3634—Electric housewares and fans	0.176	0.006	0.11
3643—Current-carrying wiring devices	0.216	0.006	0.13
3644—Noncurrent-carrying wiring devices	0.125	0.005	NA
3694—Electrical equip. for combustion eng	0.208	0.004	NA
3792—Mobile homes manufacturing	0.388	0.029	0.99
7395—Photofinishing labs	1.143	0.039	0.92
806—Hemodialysis	1.542	0.001	NA
822—Biology instructors	2.256	0.002	NA
822—Veterinary anatomist	0.002	0.000	NA

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

In addition, pursuant to the Regulatory Flexibility Act of 1980, the Assistant Secretary has assessed the expected impacts of the standard on small entities in each affected industry, and has concluded that the standard would not have a significant impact on a substantial number of small entities. Indeed, many of the regulatory provisions will have a proportionately greater effect on large establishments, especially in the wood product sectors,

where board production typically occurs in large, integrated plants.

OSHA health scientists have based their risk assessments on a study on rats performed by the Chemical Industry Institute of Technology (CIIT). A number of models for estimating a dose-response relationship using the data from the CIIT study have been presented in the Risk Assessment portion of this preamble. Although no particular estimate is preferred, for

illustrative purposes, OSHA has calculated the number of cancers that would be avoided as predicted by three of the multistage models. These calculations predict that lowering exposures in the Tier One industries will prevent from 6.5 to 47.5 cases of formaldehyde-induced cancer over 45 years. In addition, reduced exposures are expected to prevent about 6,000 cases of respiratory irritation, which will result in annual benefits of

approximately \$5.7 million. Further, the use of personal protective equipment by about 270,000 workers, in conjunction with other regulatory requirements, such as medical surveillance and training, is estimated to prevent about 11,000 cases of dermatitis, which will provide approximately \$35.5 million in annual savings. Table 8 presents OSHA's estimates of the number of employees exposed to various levels of formaldehyde, the reduced risk of cancer provided by the standard, and an enumeration of respiratory and dermatitis benefits derived from the standard.

IX. Environmental Impact

The National Environmental Policy

Act of 1969, 42 U.S.C. 4321 et. seq., requires OSHA to determine whether this standard will have a significant impact on the environment.

Formaldehyde, by nature, is volatile and does not remain soluble in water for any length of time. Consequently, formaldehyde is not considered to be a potentially hazardous wastewater effluent. Similarly, formaldehyde in waste products such as sludge would vaporize rapidly, thereby having the potential to affect air quality more than waste disposal. In any event, OSHA does not expect that the proposed action would significantly increase the amount of waste containing formaldehyde.

Although more emissions will

theoretically be removed from the workplace to the outside environment, because of the nature of formaldehyde and its ability to dissipate rapidly, no increase in the amount of formaldehyde in the ambient air is anticipated. It is not expected that compliance with the revised standard will add significantly to the levels of airborne formaldehyde that already exist in the environment as a result of automobile exhaust, cigarette smoking, and emissions from fabrics treated with formaldehyde-based resins, pressed wood products and other sources. Similarly, it is believed that the levels of ozone (a formaldehyde decomposition product) in the ambient atmosphere, will not increase significantly as a result of this action.

TABLE 8

A. Cancers Avoided by Reducing the PEL to 1.0 ppm

[Maximum Likelihood Estimate (MLE) and Upper Confidence Level (UCL)]

Industries	Employees exposed at different levels							Estimated cancers avoided		
	Parts Per Million							3-stage (MLE)	5-stage (MLE)	5-stage (UCL)
	Total	1.25	1.75	2.25	2.75	3.50	4.00			
Hardwood Plywood.....	455	455	0	0	0	0	0	0.16	0.01	0.60
Particleboard.....	301	255	46	0	0	0	0	0.14	0.01	0.46
Fiberboard.....	230	164	66	0	0	0	0	0.13	0.01	0.39
Furniture.....	1,031	873	158	0	0	0	0	0.49	0.02	1.58
Resins.....	385	192	193	0	0	0	0	0.29	0.01	0.77
Foundries.....	4,509	2,116	1,058	463	232	320	320	12.00	1.60	14.72
Laboratories.....	6,289	2,070	1,437	690	288	230	1,554	30.41	4.83	28.98
Total.....	13,180	6,125	2,958	1,153	520	550	1,874	43.62	6.48	47.51
Cancers Avoided:										
3-stage (MLE).....		2.16	3.36	2.91	2.44	5.37	27.40	43.62		
5-stage (MLE).....		0.08	0.18	0.22	0.25	0.79	4.96	6.48		
5-stage (UCL).....		8.11	7.89	4.68	2.88	4.49	19.45	47.51		

B. OTHER ANNUAL BENEFITS

[Related to PPE, Medical Surveillance, Training, etc.]

	cases avoided	value of benefits
Respiratory.....	5,911	5,650,844
Dermatitis.....	10,790	35,469,359
Total.....	16,701	41,120,203

OSHA concludes that, as a result of this action, there will be no significant impact on the general quality of the human environment outside the workplace, particularly in terms of ambient air quality, water quality, or solid waste disposal. No comments made at the public hearing or submitted to the record contradict this conclusion.

X. Summary and Explanation of the Standard

The following sections of the

preamble discuss the individual provisions of the final standard for formaldehyde. Each section includes an analysis of the record evidence and the reasons underlying OSHA's adoption of these individual regulatory requirements.

Overview

The final standard applies to all occupational exposures to formaldehyde, including those resulting

from formaldehyde gas, solutions, and materials releasing formaldehyde. The standard contains two permissible exposure limits (PELs) for formaldehyde: an 8-hour time-weighted average (TWA) exposure limit of 1 ppm and a 15-minute short-term exposure limit (STEL) of 2 ppm.

Engineering and work practice controls are the preferred methods of compliance, respirators are required where engineering and work practice controls are not feasible and respirators are necessary to achieve compliance with the PELs. In addition, employers must perform employee exposure monitoring, unless they can demonstrate by means of objective data that such monitoring is not necessary in their workplaces. Other requirements in the standard include provisions to establish regulated areas and medical surveillance programs. The final rule specifies how affected employers can comply with OSHA's generic hazard communication standard (29 CFR 1910.1200). The final rule also specifies how affected employers can comply with other existing OSHA standards (29 CFR 1910.132, Protective equipment; 29 CFR 1910.133, Eye and face protection; and 29 CFR 1910.134, Respiratory protection) that may be relevant to workplaces where employees are exposed to formaldehyde.

Several provisions have been modified from the proposed standard in response to testimony and comments submitted to the record, the availability of new data and information, or the need to clarify language. The reasons for these changes are described below. The requirements of the final rule are considered both necessary and appropriate to provide adequate protection to employees exposed to formaldehyde.

Proposed Regulatory Alternatives A and B

In the preamble to the proposed rule [50 FR 50468-69], OSHA noted that the regulatory options before the Agency were broad, ranging from a change in the PELs for formaldehyde in 29 CFR 1910.1000, Table Z-2, to adoption of a full health standard with the provisions found in standards for carcinogens. The preamble indicated that OSHA's choice of regulatory strategy would depend on the Agency's decision to regulate formaldehyde as an irritant, a carcinogen, or as both. OSHA invited the public to comment on "the entire spectrum of regulatory possibilities" before the Agency.

If OSHA adopted the Alternative A strategy—regulation of formaldehyde as an irritant—the preamble stated that "it

might be sufficient to lower the permissible exposure limits for formaldehyde contained in Table Z-2 * * * and to rely on existing sections of the general industry standards, such as §§ 1910.132, 1910.133, 1910.134 and 1910.1200, to provide the supplementary coverage needed for employee protection" [50 FR 50468].

OSHA also stated that if available evidence was sufficient to conclude that "formaldehyde is an animal carcinogen and should be treated for regulatory purposes as a potential occupational carcinogen," Alternative B would be appropriate [50 FR 50469]. Proposed Alternative B recognized formaldehyde's role as a potential human carcinogen, skin sensitizer and irritant, and eye and respiratory system irritant. Proposed Alternative B was a comprehensive OSHA health standard, containing PELs and provisions for employee monitoring, medical surveillance, protective equipment and clothing, hygiene facilities, and hazard communication.

The final rule regulates occupational exposures to formaldehyde on the basis of formaldehyde's potential carcinogenicity, as well as its ability to act as a strong irritant and sensitizer of the skin, eyes, and respiratory system (see the Health Effects section, above).

Many industry participants favored lowering the PELs for formaldehyde through adoption of Alternative A [Exs. 77-2; 77-15; 77-33; 77-34; 80-1; 80-4; 80-5; 80-6; 80-15; 80-16; 80-23; 80-24; 80-26; 80-30; 80-38; 80-40; 80-43; 80-47; 80-55; 80-58; 80-59; 80-61; 80-63; 80-64; 80-67; 80-68; 80-69; 80-71; 80-72; 80-76; 80-77; 80-78; 80-79; 80-80; 80-83; 80-85; 80-86; 80-89; 80-100; 80-132; 80-261; 80-303; 86-7; 140; 150; 171; 201-9; Tr. 5/13/86, p. 62; Tr. 5/13/86, p. 137]. The reason most often presented to explain why these rulemaking participants preferred Alternative A to Alternative B was that, in their opinion, occupational exposure to formaldehyde presented no risk of cancer [Exs. 77-2; 80-1; 80-5; 80-6; 80-30; 80-58; 80-61; 80-68; 80-71; 80-72; 80-76; 80-77; 80-83; 80-85; 80-86; 80-89]. Typical of these comments was the statement submitted by John T. Barr, Manager of Air Products and Chemicals:

We support regulatory alternative A. We do not believe that current occupational exposures to formaldehyde present a risk of cancer to humans, but we believe that proper steps need to be taken to assure that this safe condition continues [Ex. 80-1, p. 3].

Some participants felt occupational exposures to formaldehyde at current levels present only a risk of "minor" irritant effects [Exs. 77-33; 80-43; 80-55;

80-59; 80-67; 80-80; 80-303; Tr. 5/13/86, p. 66].

Some participants believed Alternative A was attractive because it would be easy to implement [Exs. 77-34; 80-5; 80-23; 80-26]. For example, Leon J. Manich, Technical Director of the Louisiana-Pacific Corporation, a manufacturer of medium-density fiberboard, endorsed the adoption of Alternative A because, in his view, it would "protect the public and serve as a workable approach for industry" [Ex. 80-5, p. 1].

The costs associated with Alternative B's ancillary provisions, *i.e.*, requirements such as emergency plans, employee monitoring, and hazard communication, were emphasized in the submittal of Norman Newhouse, an Illinois lumber dealer. Mr. Newhouse favored adoption of Alternative A because the costs of Alternative B were likely to be "considerable" [Ex. 80-132].

Other commenters favored a simple revision of the Z-2 table limits for formaldehyde because they felt that other OSHA standards, such as the generic hazard communication standard and §§ 1910.132, 1910.133, and 1910.134, already provided formaldehyde-exposed workers with adequate protection [Exs. 80-47; 80-71; 80-79; 140].

Michael Farrar, Vice President of the American Paper Institute and the National Forest Products Association, trade associations representing the pulp, paper, paperboard, and solid wood industries, urged the adoption of Alternative A [Ex. 80-63, p. 6] so that formaldehyde would not have to be treated as a carcinogen under OSHA's generic Hazard Communication standard (29 CFR 1910.1200). However, as is discussed elsewhere in more detail, formaldehyde clearly should be regarded as a potential human carcinogen (see Health Effects and Significance of Risk discussion above). Employers will have to treat formaldehyde in accordance with the Hazard Communication standard's requirements for carcinogens since it meets the criteria set out in that standard. Regulating formaldehyde only as an irritant would be grossly inconsistent with the record and with the intent of the Hazard Communication standard.

Four principal beliefs appear to underlie the preference of several rulemaking participants for the adoption of Alternative A: (1) Employers should be allowed the maximum amount of discretion in determining conditions in their workplaces; (2) formaldehyde is not a carcinogen; (3) formaldehyde's transient irritant effects do not pose a

significant risk of material health impairment to exposed workers; and (4) the only measure necessary to protect workers against the non-cancer effects of formaldehyde exposure is a reduction in the PELs. As described in the Health Effects and Significance of Risk portions of this preamble, however, the evidence in OSHA's record clearly establishes that formaldehyde poses a significant risk of material impairment of health at the old PELs of 3 ppm (8-hour TWA), 5 ppm (ceiling), and 10 ppm (peak). In addition, evidence in the record indicates that merely reducing airborne exposure, as proposed in Alternative A, would not address the risk of skin diseases and other irritation and sensitization caused by dermal contact with formaldehyde.

The evidence in the record as a whole does not support the adoption of Alternative A. In short, the Agency has found that: (1) Some employers have not exercised appropriate discretion to protect their employees; (2) formaldehyde is a potential human carcinogen; (3) formaldehyde-induced irritation and sensitization can constitute material impairment of health; and (4) a comprehensive OSHA standard is needed to protect workers. OSHA has rejected Alternative A because the Agency believes that a change in the PELs alone will not adequately protect the health of formaldehyde-exposed workers.

As Michael Larsen, a certified industrial hygienist (CIH) and Vice President and Director of Industrial Hygiene Services for the Occupational Medical Center, Inc., stated at the hearings.

" * * * it would indeed seem inappropriate to classify formaldehyde solely as a simple irritant gas * * *. More importantly, * * * reducing formaldehyde exposure in Table Z-2 to an appropriate level would not provide small businesses with sufficient guidance * * * to adequately protect their employees [Tr. 5/7/86, pp. 6-7].

There was widespread support in the record from public interest groups, professional associations, employee unions, and others for the adoption of proposed Alternative B [Exs. 77-11, (NIOSH); 77-31 (United Paperworkers International Union); 77-35 (College of American Pathologists); 77-38 (Amalgamated Clothing and Textile Workers Union); 77-40 (American Nurses' Association); 80-88 (International Ladies Garment Workers Union); 86-1 (Public Citizen Health Research Group); Tr. 5/7/86, p. 5 (the Occupational Medical Center); Tr. 5/8/86, p. 5 (NIOSH); Tr. 5/14/86, p. 166 (AFL-CIO); Tr. 5/16/86, p. 2 (United Furniture Workers of America)].

Several rulemaking participants pointed out that formaldehyde meets established criteria for classification as a potential carcinogen. For example, Dr. Michael Silverstein, Assistant Director of the Health and Safety Department, UAW, asserted that "formaldehyde must be regulated as a presumptive human carcinogen" because "indisputable animal carcinogenicity data * * * [are] sufficient to render such a judgment" [Tr. 5/14/86, pp. 191-200]. Ms. Jamie Cohen, Project Coordinator of the United Furniture Workers of America, also urged OSHA to promulgate a comprehensive standard because formaldehyde is a carcinogen [Tr. 5/15/86, p. 2]. Margaret Seminario, Associate Director of the AFL-CIO's Department of Occupational Safety, Health, and Social Security, reported that the AFL-CIO considers formaldehyde a potential occupational carcinogen under terms of OSHA's cancer policy [29 CFR 1990] and believes that the evidence clearly demonstrates that exposures allowed under the old PEL "pose a significant risk to workers" [Tr. 5/14/86, p. 166].

NIOSH was a major proponent of the view that formaldehyde should be handled as a carcinogen in occupational environments. NIOSH recommended that formaldehyde exposure "be controlled to the lowest feasible limit" on the basis of its classification as a carcinogen [Ex. 77-11, p. 1]. NIOSH submitted these comments in fulfillment of its statutory responsibilities under the OSH Act, which require the Institute to:

develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience [Sec. 20(a)(3)].

The American Nurses' Association [Ex. 77-40] and the College of American Pathologists [Ex. 77-35], organizations of health professionals, also endorsed NIOSH's approach.

In the opinion of several commenters, even Alternative B is not sufficiently protective against formaldehyde's adverse health effects [Exs. 80-36; 80-50; 86-1; 101; Tr. 5/7/86, pp. 5-6; Tr. 5/9/86, p. 86]. These participants urged OSHA to adopt a standard that would include at least the ancillary provisions of Alternative B along with a more stringent PEL than either TWA proposed by OSHA (1 or 1.5 ppm). Public Citizen Health Research Group, an advocacy organization for consumer and occupational health, urged regulation of formaldehyde both as a potential human

carcinogen and an irritant, and expressed strong reservations about the adequacy of the proposed Alternative B PEL of 1 ppm (8-hour TWA) [Ex. 101, p. 2]. Thurman B. Wenzl, Industrial Hygienist with the International Chemical Workers Union, stated that a STEL of 2 and TWA lower than 1.5 ppm were needed to reduce the risk of sensitization and severe irritation that frequently occur at levels below the old TWA of 3 ppm. Mr. Wenzl also pointed out that, as proposed, both alternatives A and B did not include a STEL, and would permit high short-term exposures of up to 16 ppm for 30 minutes [Ex. 80-50, pp. 1-2].

In addition, OSHA's review of the record indicates that reduction of the exposure limits in Table Z-2 alone would not provide protection against dermal sensitization and other non-cancer effects. OSHA bases this conclusion, in part, on the testimony of experts at the rulemaking hearing. For example, Edward A. Emmett, M.D., Director of the Center for Occupational and Environmental Health at Johns Hopkins University, stated that:

Regulatory Alternative A * * * would ignore or discount all other effects of formaldehyde including burns to the eye, sensitization of the skin, irritation of the skin, and indeed the carcinogenicity of formaldehyde in experimental animals which has led to a presumption that it's a potential human occupational carcinogen.

For example, Regulatory Alternative A does not contain any provisions to decrease skin exposure, and reducing or controlling air levels of formaldehyde will have little or no effect on protecting the skin on direct contact with sources of formaldehyde [Tr. 5/6/86, pp. 68-69].

OSHA has carefully evaluated the comments regarding the proposed regulatory alternatives, and has, in addition, weighed the evidence on the health effects associated with workplace exposures to formaldehyde. The Agency concludes that only a comprehensive standard can decrease the risks associated with all of these adverse health effects; a regulatory alternative that simply lowers the PEL cannot protect workers against the broad range of formaldehyde-induced health effects.

The ancillary provisions contained in a full health standard are especially appropriate in the regulation of an irritant and sensitizer such as formaldehyde. For example, training and personal protective equipment provide important worker protection when irritants, which by definition are corrosive in action, inflaming the moist mucous surfaces of the body [Ex. 73-175,

p. 20], are being handled in the workplace. The inclusion of such requirements is consistent with section 6(b)(7) of the OSH Act, which specifies that:

Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate, such standard shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees. In addition, where appropriate, any such standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure.

Based on the record as a whole, the Agency concludes that regulation of formaldehyde as a potential human carcinogen, an irritant, and a sensitizer is both necessary and appropriate to protect workers' health and functional capacity. The best available evidence, discussed above in the health effects section, clearly dictates promulgation of a final rule that will address formaldehyde's potential adverse effects, including skin, eye, and respiratory irritation; dermal and pulmonary sensitization; and cancer.

Paragraph (a)—Scope and Application

Like the proposal, the final standard applies to all occupational exposures to formaldehyde, including those in general industry, maritime, and construction. The language in paragraph (a)(1) has been altered from that of the proposal to clarify that the standard applies to a single, specific chemical entity, formaldehyde, with a Chemical Abstracts Service Registry number of 50-00-0.

Employee exposure to formaldehyde can occur in a number of ways. For example, formaldehyde production workers are potentially exposed to formaldehyde gas; workers who handle formaldehyde solutions, paraformaldehyde, or materials containing resins or glues that have releasable formaldehyde may also be exposed to gaseous formaldehyde. These solid and liquid products may also present a risk from dermal contact with formaldehyde. The final standard

is designed to protect against all hazards from formaldehyde exposure, regardless of the source. (Of course, the standard does not necessarily protect against all of the hazardous ingredients in a mixture).

The Agency's determination that all occupational exposures should be covered by the final rule is consistent with evidence in the record that the risk of formaldehyde exposure is related to the degree of exposure rather than to the operation, workplace, or segment of industry in which such exposure occurs. OSHA's position on the appropriate scope of the standard is unchanged from the proposal, and the Agency received only a few comments on this subject.

The proposed rule explicitly stated that OSHA intended the standard to apply to the construction industry. The proposal also noted that OSHA's Advisory Committee on Construction Safety and Health had requested that OSHA develop a separate standard for formaldehyde for the construction industry or that, as an alternative measure, the Agency adopt "the most protective standard available" [50 FR 50414].

Despite OSHA's request for information on how the standard should be modified to consider the unique characteristics of the construction industry [50 FR 50413], OSHA received very little information on this industry and has reached and has reached the conclusion, based on the Agency's evaluation of the types of construction jobs known or suspected of having some potential for formaldehyde exposure, that the impact on this industry is small. For example, Scott Schneider, an industrial hygienist with the United Brotherhood of Carpenters and Joiners of America testified that there are several construction jobs where there is potential formaldehyde exposure, including laying floors in a confined space when glues containing formaldehyde are used, blowing of urea-formaldehyde foam insulation into walls, and cutting and sanding wood products containing formaldehyde [Tr. May 14, 1986, pp. 137-138]. It is apparent that in the past construction workers could have received substantial exposures to formaldehyde. However, negative publicity surrounding the use of UFFI has virtually eliminated this use of formaldehyde. Recent evidence on the generation of "particleboard aerosol" by a sanding process conducted under laboratory conditions indicated all airborne formaldehyde concentrations below 1 ppm [Ex. 201-5A], showing that under the more typical intermittent exposure situation during actual carpentry, exposures should be well

below the action level of 0.5 ppm. With the exception of industrial construction, which can also be hazardous because of the presence of formaldehyde from the operation, there appears to be little impact that the formaldehyde standard will have on the construction industry. OSHA's analysis of the data available suggests that most construction activities result in worker exposure well below 0.5 ppm. To the extent that there are any unique operations, such as construction-related maintenance, or an increase in the use of formaldehyde-releasing resins in a confined area, the general industry standard is being applied to construction (see 1910.19).

A representative of the maritime industry, Hal Draper, observed that:

it would be impractical if not impossible for the marine cargo handling industry to meet the requirements of the proposed formaldehyde standard due to the use of casual labor and mobile work sites with remote possibility of employee exposure to formaldehyde [Ex. 80-53, p. 2].

OSHA has chosen not to write a separate standard for the construction or maritime industries, both because commenters did not suggest any specific modifications to the standard to adapt it to the mobile worksite environment typical of these sectors and because the Agency believes that the final standard is flexible enough to present few compliance burdens for employers in these sectors.

The standard has been tailored so that certain provisions become inapplicable or have only limited applicability when employee exposure is low. For example, routine medical surveillance is triggered by employee exposures above the action level. Thus, the standard is more stringent where employee exposures to formaldehyde present higher risk and becomes more flexible in situations where exposure and risk decrease. The final rule has been structured so that compliance burden imposed by the standard is directly to the potential hazard posed by occupational exposure to formaldehyde in each particular employment setting. The Agency believes that, because of this approach, no significant compliance burden will be imposed on construction or maritime employers whose employees, in general, are exposed to formaldehyde only at concentrations believed by OSHA to be well below the PELs.

In the proposal, OSHA expressed the intent to fully cover laboratory uses of formaldehyde under the standard [50 FR 50470]. Further, it was proposed that the limited coverage of laboratories under Hazard Communication be enlarged in the formaldehyde standard so that

laboratories using formaldehyde would be subjected to all of the Hazard Communication provisions rather than the limited provisions found in 29 CFR 1910.1200(b)(3). For reasons discussed more fully in the Hazard Communication section of the summary and explanation, OSHA has decided not to enlarge the hazard communication coverage of laboratories in this final rule.

The Standard Oil Company, which has several production and laboratory facilities where formaldehyde is used, requested special consideration of laboratories. According to Standard Oil:

The Standard Oil Company does not believe that laboratory workplaces should be subjected to the same requirements as other workplaces within the scope of the proposed standard.

In contrast to typical manufacturing locations, work practices, quantities of formaldehyde handled and exposure controls are vastly different for a laboratory. Small quantities of formaldehyde are used in most quality control and research laboratories; the formaldehyde is handled by highly trained technicians and chemists; the exposure to formaldehyde, is usually below sensory irritation levels; the duration of the work task is short, usually lasting only a matter of minutes; and some labs require handling formaldehyde in a laboratory exhaust hood. Based on the small amount of formaldehyde used, the concentration of formaldehyde in the lab hood exhaust is minimal [Ex. 80-89, pp. 2-3 of attached comments].

In its description, Standard Oil presents the case of a typical laboratory where the use of any one chemical, in this case formaldehyde, is very incidental and a minor part of the overall exposure potential. There are undoubtedly many such circumstances where formaldehyde solutions, in minor quantities, are used as one of many reagents or where very small amounts of formaldehyde are present as preservatives. These are precisely the circumstances that the Toxic Substances in Laboratories proposal [51 FR 26660, July 24, 1986] attempted to address; namely the nonroutine use of small amounts of numerous toxic substances.

OSHA is mindful of the potential for overlap between procedures required in laboratories by the formaldehyde standard and the procedures under the laboratory standard. In finalizing the laboratory standard, OSHA will make every effort to assure that there are not conflicts or duplicative requirements.

However, OSHA has identified one laboratory use of formaldehyde where the severity of the exposures to employees have tended to be even greater than the typical exposures that occur within general industry. This is the use of solutions containing formaldehyde to preserve tissue and the

subsequent handling of such tissues. Exposed employees are laboratory workers and teachers in histology, pathology, and anatomy laboratories.

Evidence submitted to OSHA's record [Exs. 78-20; 78-54; 85-29; 91; 128] clearly confirm that work in such laboratories may result in routine exposure to formaldehyde, both by inhalation and by dermal contact. Furthermore, numerous examples of exposure to extremely high airborne concentrations of formaldehyde were found [Exs. 42-95; 42-96; 175-17; 175-18], as was evidence of formaldehyde-induced irritation and skin disorders and sensitization reactions [Exs. 78-20; 78-54; 85-29]. These problems were found despite the very high level of training and education of some of the individuals who were being exposed.

While many biology laboratories have installed adequate engineering controls and require their employees to observe good work practices, others have not done so. Dr. Melvin First, of the Harvard School of Public Health and an expert witness in industrial hygiene and engineering controls, testified that 17 percent of a group of 637 personal samples from hospital laboratories were above the 8-hour TWA of 1 ppm. In Dr. First's opinion, these results showed that a "significant number of hospital laboratories are using poor work practices or lack of functional hoods" [Tr. May 16, 1986, pp. 56-132].

Given the severity of the hazards found and the ubiquitous presence of large amounts of formaldehyde solutions in such laboratories, OSHA believes that formaldehyde use in histology, pathology, or human or animal anatomy laboratories (including teaching laboratories) should not be included in the scope of the proposed Toxic Substances in Laboratories standard. These facilities and operations will be covered under the formaldehyde standard. Given the significance of the exposures and the severity of the effects seen in such workers, limiting their coverage under the formaldehyde standard would be inappropriate.

As to other laboratory uses of formaldehyde, it is unclear whether such uses would be better accommodated under this final rule on Occupational Exposure to Formaldehyde or the more general Toxic Substances in Laboratories rule when it is promulgated. Moreover, any category of laboratory that is eventually exempted from the Toxic Substances in Laboratories standard will automatically be covered by this standard to the extent there are occupational exposures to formaldehyde. This issue will be

considered further as part of the promulgation of the Toxic Substances in Laboratories regulation. OSHA believes that most laboratories (except histology, pathology, and anatomy) are already in compliance with the provisions of the formaldehyde standard. However, to avoid imposing start-up costs for other laboratories under this standard which may be unnecessary if the formaldehyde standard is superseded by the general standard for laboratories, OSHA is extending the compliance date for other laboratories to September 1, 1988, at which time the Laboratory standard is expected to be in effect. Given the severity of the health effects projected to occur at the existing 3 ppm TWA, 5 ppm ceiling, and 10 ppm peak, however, OSHA is requiring all laboratories to be in compliance with the new PELs of 1 ppm as a TWA and 2 ppm as a STEL. Clearly, formaldehyde is a very toxic substance which must be handled extremely carefully. While many other labs are presently in compliance with this standard, some are not, and OSHA is hesitant to create an open-ended period where some of the "other" laboratory employees will have no protection from some of the adverse effects of formaldehyde, especially those protections in this rule triggered by concern about the dermal effects associated with formaldehyde exposure. Therefore, should the Toxic Substances in Laboratories final rule not be in effect by September 1, 1988, this rule (29 CFR 1910.1048) will become effective for such other laboratories so that their employees will be appropriately protected.

The Society of the Plastics Industry, Inc. (SPI) and the E.I. du Pont de Nemours Company requested an exemption for the thermoplastic acetal molding industry from the scope of the standard. The Society based its request, in part, on the assertion that small businesses in this sector would have difficulty in fulfilling the standard's monitoring requirements. In addition, Du Pont and SPI stated that exposures in workplaces in this sector were not above 1 ppm PEL (8-hour TWA) and that the sector was comprised of small businesses without the capital or personnel resources to perform monitoring or medical surveillance [Ex. 80-64, p. 29]. However, data [Ex. 80-80] submitted with the Society's request show that employee exposures in these operations do exceed the new PELs at times. Therefore, OSHA believes it would be inappropriate for OSHA to grant the requested exemption. OSHA notes, however, that to the extent a particular workplace has exposure

below the action level, the compliance burden will be minimal.

The Scott Paper Company urged OSHA to exempt paper products from the scope of the standard's hazard communication requirements because "the use of paper products under normal conditions will not result in exposure of workers to formaldehyde at levels even remotely approaching" the action level or PELs proposed by OSHA [Ex. 80-62, pp. 1-2]. Where paper products emit only trivial amounts of formaldehyde, the final rule's hazard communication provisions will not be triggered. Furthermore, the final standard exempts employers whose workplaces contain only mixtures or solutions composed of less than 0.1 percent formaldehyde or materials incapable of releasing formaldehyde at concentrations at or above 0.1 ppm from compliance with the hazard communication provisions. Use of this regulatory approach means, in effect, that the great majority of downstream uses of paper products will effectively be exempted from the standard. Evidence in the record, however, indicated that certain workers involved in the production of paper products may be exposed to significant levels of formaldehyde [Ex. 149, Appendix A]. In addition, the United Paperworkers International Union (UPIU) testified that many industrial hygiene practices and procedures used in this sector are inadequate [Ex. 149, Appendix B]. Accordingly, it would be inappropriate for OSHA to exempt this industry from coverage.

The American Furniture Manufacturers Association (AFMA) believed that the occupational exposures resulting from downstream uses of formaldehyde-bearing products are sufficiently different from those of formaldehyde producers to warrant separate ancillary requirements (*i.e.*, other than the PELs). The AFMA felt that the proposed standard's protective clothing, emergency, and waste disposal provisions were inappropriate for furniture manufacturers [Ex. 80-68, pp. 5-6]. In general, OSHA agrees with AFMA that these provisions are much less important in a plant that assembles furniture than they are where large quantities of formalin solution are being handled. This does not mean that it is necessary to design industry-specific standards. The general standard's provisions require only that the employer provide the protection needed given the individual circumstances.

A representative of the maritime industry, Hal Draper of the West Gulf Maritime Association, asked that the final rule contain an exemption for "the

storage, transportation, distribution, or sales of formaldehyde in intact containers" from all of the provisions of the final rule except the hazard communication and emergency requirements [Ex. 80-53, p. 2]. Mr. Draper noted that such a "partial exemption" would be in keeping with similar language in OSHA's proposed benzene standard [50 FR 50512] and in other OSHA standards [Ex. 80-53, p. 2]. With the exception of the need to make an objective determination that the containers are, in fact, intact, the formaldehyde standard already provides the relief requested by Mr. Draper. Employers whose only use of formaldehyde involves intact containers would have minimal obligations under the standard.

On the basis of OSHA's analysis of these comments, the Agency believes that, at the present time, a single formaldehyde standard applicable to all occupational exposures to formaldehyde is most appropriate and protective of employee safety and health. OSHA believes that all exposed employees, including those exposed only infrequently, should be provided with some basic protection because some of the adverse effects of exposure to formaldehyde are acute and arise after only a few minutes of exposure.

The major change to the scope and application section of the standard since the proposal is the deletion of the proposed exemption for: (i) Liquid formaldehyde solutions containing less than 0.1 percent formaldehyde, and (ii) solid materials made from or containing formaldehyde that are incapable of releasing formaldehyde into the workplace air.

OSHA received many comments on this proposed exemption [Exs. 80-21; 80-34; 80-35; 80-37; 80-54; 80-56; 80-59; 80-63; 80-64; 80-69; 80-72; 80-303; Tr. 5/8/86, p. 18] from participants requesting that OSHA extend the proposed 0.1 percent exclusion for liquid formaldehyde solutions to solids containing a similar percentage of formaldehyde [Exs. 80-54; 80-56; 80-59; 80-64; 80-69; 80-72; 80-303]. The major concern expressed was that, without an exclusion, employers would be required to label articles such as textiles, apparel, envelopes, and other common items routinely used by consumers [Exs. 80-56; 80-59; 80-63; 80-72; 80-303]. Evidence in the record indicates, however, that a 0.1 percent exemption for solids which continue to release formaldehyde over long periods of time is inappropriate and potentially dangerous. For example, all textiles would be exempt under such a definition according to representatives

of the National Cotton Council [Tr. 5/14/86, p. 76], but the record contains numerous reports of formaldehyde-induced illnesses among garment workers (see, for example, the NIOSH HHEs (Exs. 78 and 85) cited in Health Effects). OSHA's generic Hazard Communication standard clearly covers textiles used in apparel manufacture, and the record in this rulemaking clearly supports such coverage.

OSHA's response to these commenters has involved two changes to the final rule. First, the Agency has refined the definition of formaldehyde so that it is clear that the standard applies only to formaldehyde; it does not cover all of the other substances that may be present in a mixture. Even though OSHA's generic Hazard Communication standard exempts components of mixtures present in concentrations of less than 0.1 percent by weight, an employer is still obligated to recognize the minor component as hazardous if employees are exposed at airborne concentrations over either PEL. The best method available to assure that such hazardous exposures are not occurring is the use of employee exposure monitoring, or at the least, objective data, which the formaldehyde standard assures will be collected for formaldehyde. Accordingly, the exemption has been moved to paragraph (m)(1)(i), which defines, for the purposes of hazard communication, "formaldehyde gas, all mixtures or solutions composed of greater than 0.1 percent formaldehyde, and materials capable of releasing formaldehyde into the air under any normal condition of use at concentrations reaching or exceeding 0.1 ppm" as a health hazard.

Although use of this definition of a formaldehyde health hazard will not ensure that every employer is alerted to the presence of each and every product that contains even a trace of formaldehyde, OSHA believes that a manufacturer, importer, or distributor of a formaldehyde-bearing product would be aware if a product is capable of emitting sufficient formaldehyde to pose a health hazard.

Paragraph (b)—Definitions

In the final standard, the definitions of "Assistant Secretary", "Authorized persons", and "Director" remain unchanged from the proposal.

The definition of an "action level" as half the PEL, calculated as an eight-hour time-weighted average (TWA), is also essentially unchanged from the proposal. An action level is an exposure limit above which the monitoring and annual training provisions of the

standard apply. If, on the basis of initial monitoring results or objective data, employee exposures are found to be below the action level of 0.5 ppm and below the STEL, the employer is permitted to discontinue monitoring and certain employee training practices. Although employers are not obligated to achieve the action level, regulatory use of this level provides an incentive for employers to reduce exposures voluntarily where it is possible for them to do so.

OSHA's intent in adopting an action level is to increase the cost-effectiveness of the standard while simultaneously enhancing employee protection. As the proposal noted [50 FR 50470], there are two rationales behind the action level concept: one statistical and the other toxicological. According to the proposal:

The statistical basis for establishing an action level is that measurements of employee exposure can vary considerably for a number of reasons, including process variations, sampling and analytical methods limitations, and seasonal changes. Even when all measurements on a given day may fall below the PEL, there is some chance that on another day, when exposures are not measured, the employee's actual exposure may exceed the PEL. It has been shown that when measured levels are greater than one-half the PEL, the employer cannot have a high degree of confidence that employees are not being exposed to formaldehyde concentrations in excess of the PEL during at least some part of the work week when exposures are not measured. Conversely, when the employer has collected sufficient samples to take into account the various process and sampling related variabilities, and the concentrations are below the action level, the employer can have a reasonable degree of confidence that the PEL is not being exceeded on days when measurements are not taken.

Thus, including an action level in the standard enables the Agency to help employers use their resources most efficiently and effectively. By setting a numerical action level and designating the number of times monitoring must be performed in a year, OSHA relieves the employer from having to make complex statistical calculations to determine if his or her workplace is truly below the PEL. Employers who meet OSHA's action level criterion can presume that they are not overexposing their employees; without an action level, employers would have no practical assurance that a decision to terminate monitoring is appropriate.

The action level is also beneficial to employees, since they are placed at lower risk when their employers can reduce workplace exposures below the action level. Employers therefore, can

focus their protective efforts on those employees who are especially sensitive to formaldehyde. As explained in the preamble to the proposal,

* * * the toxicological basis for an action level takes into account the variability of individuals in reacting to a toxic substance when it is inhaled or otherwise taken into the body. Experiments conducted on laboratory rodents minimize these inherent differences in genetic composition by selecting inbred animals from the same strain and same colony for testing. Their environments are further controlled in terms of exposures to other substances, to diet, to diurnal variations, and to temperature and humidity. Because all of these factors are variables in humans, there is a much wider range to responses to formaldehyde in workers than in test animals. In particular, these differences are seen in employee complaints and signs and symptoms of irritation from formaldehyde [50 FR 50470].

As discussed in the Health Effects section of this preamble, adverse health effects occur at levels between 0.5 and 1 ppm. Approximately 10 percent of workers exposed at or above 0.5 ppm but below 1 ppm will experience discomfort of the respiratory tract and eye irritation. Occupational asthma has also been documented in workers exposed below 1 ppm. Thus, the use of an action level provides an extra margin of safety for these hypersensitive individuals.

Many participants supported the inclusion of an action level in this standard [Exs. 77-2; 77-11; 77-12; 77-22; 77-32; 77-34; 77-37; 80-21; 80-56; 98; Tr. 5/7/86, p. 13]. For example, the UAW commented that the standard should "include an action level below the PEL based on OSHA's current judgment of exposure levels associated with various health effects which may occur at levels below the PEL" [Ex. 77-12, p. 2]. The Air Transport Association recommended that OSHA adopt an action level below which training, physical examinations, and other requirements would not apply, because such a level would provide employers with a positive incentive to minimize hazards and would also reduce costs [Ex. 77-22].

Other commenters opposed the adoption of an action level [Exs. 77-9; 77-10; 77-14; 77-17; 77-18; 77-19A; 77-23; 77-24; 77-25; 77-28; 80-11; 80-59; 80-60; 80-65; 80-68; 80-79; 80-257; 80-261; 80-303; 85-111B; 86-23; 98; 113; Tr. 5/12/86, p. 133; Tr. 5/15/86, p. 2]. Some commenters felt that an action level would provide no additional protection [Ex. 77-17] or that it is unnecessary [Exs. 77-14; 77-23; 85-111B]. Several participants believed that having an action level would actually impose, rather than mitigate, regulatory costs [Exs. 77-21; 77-25; 77-28; 80-26]. For

example, States Industries [Ex. 77-25] stated that the action level would increase production costs because "there would be a costly medical and technical program coupled with the action level concept." In addition, Temple-Eastex [EX. 77-28] commented that an action level "would impose onerous monitoring on the company to show compliance with an action level set at 0.5" OSHA believes that these comments reflect misunderstanding of the action level concept. The use of an action level permits some of the standard's major provisions, such as annual training, to be focused solely on the higher risk employee rather than all employees with exposure to formaldehyde.

Some respondents objected to an action level because they believed that formaldehyde is not a potential human carcinogen and that action levels were appropriate only for chemicals associated with a significant risk of cancer or with chronic health hazards [Exs. 77-19A; 77-23; 80-258; 80-261; 80-303]. For example, James Leker, representing the Masonite Corporation, a manufacturer of wood products, stated that "the proposal of an 'Action level' for a chemical only proven to be an irritant is difficult to understand" [Ex. 80-258, p. 3]. Along similar lines, James MacRae, from the Office of Management and Budget (OMB), stated that:

We are uncertain as to the need in this rulemaking for an action level * * *. If the risks below the PEL cannot be shown to be significant, then extra requirements below the PEL will not improve worker protection [Ex. 80-261, pp. 83-84].

As discussed in the Significance of Risk section, however, OSHA has determined that employees exposed over their working lifetimes to formaldehyde at levels below the PELs may remain at significant risk of incurring health impairments.

Clare Sullivan, Occupational Health Specialist, and Steve Trawick, Director of Safety and Health, for the UPIU, stated the union's position that:

There is no safe level of a carcinogen. Any level of exposure to formaldehyde should trigger monitoring, methods of compliance, education, personal protective clothing, and medical surveillance [Ex. 80-65, p. 2].

OSHA believes that action levels are particularly appropriate when there is a clearly defined threshold level below which no illness has been demonstrated. Thus, an action level is especially appropriate for acute effects, where both the statistical and toxicological bases for such a level apply. However, the Agency's decision to include an action

level in this standard is based on the belief that this is the most cost-effective approach to adopt to ensure that employers allocate scarce safety and health resources to higher risk workers. Further, as discussed above, deleting the action level from the standard would remove incentives to reduce formaldehyde exposures below the action level.

Several rulemaking participants emphasized the beneficial function of an action level [Exs. 77-11; 77-12; 77-22; 77-32; 77-34; 80-21; Tr. 5/7/86, p. 13]. For example, J. Donald Millar, M.D., Director of NIOSH, strongly endorsed the action level concept:

The action level is an effective means by which the employer can monitor the effectiveness of existing controls and, in the event of exposures beyond the action level concentration, take remedial action [Ex. 77-11, Attach. 1, p.1].

The National Kitchen Cabinet Association (NKCA), a national trade association representing 281 companies, stated

* * * NKCA feels that it would be appropriate to establish an action level below which firms are relieved of those regulatory burdens [Ex. 77-34, p. 4].

In the final rule, OSHA has used the action level to trigger several of the standards major provisions, including annual training and the initial monitoring requirement. This is consistent with the Agency's traditional practice with regard to action levels.

There was disagreement among commenters who supported the action level concept, regarding the level at which the action level should be set [Exs. 77-2; 77-24; 80-36; 80-37; 80-48; 80-56; 80-59; 80-76; 80-86]. Several commenters maintained that an action level below 1 ppm would not be useful to employers [Exs. 77-2; 77-24], while others felt that an action level set either at 75 percent of the PEL [Ex. 80-59] or at the PEL itself [Ex. 80-52] would be appropriate. On the other hand, Peter Breysse, Associate Professor Emeritus of the School of Public Health and Community Medicine at the University of Washington, testified that the long-term health effects of formaldehyde exposure warrant an action level of 0.2 ppm [Tr. 5/7/86, pp. 165-166].

OSHA rejects the idea that an action level should be closer to the PEL than 50 percent of the 8-hour TWA. The closer the action level is to the PEL, the greater the amount of exposure monitoring that OSHA would have to require to ensure compliance with the TWA on unmeasured days. This approach would not be cost effective or protective of worker health.

A few employees remain at risk from exposures to formaldehyde at levels below 0.5 ppm, and the final rule provides some protection for these workers. While such toxicological considerations might support setting an action level lower than one-half the TWA, OSHA generally sets the action level at one-half the TWA because the Agency believes that figure strikes the appropriate balance between considerations of employee protection, degree of hazard, and cost effectiveness. OSHA reaches the same conclusion in this case.

OSHA believes that the record supports setting an action level at 50 percent of the TWA. Meeting the action level is voluntary (*i.e.*, OSHA does not issue citations for failure to comply with an action level). Employers who do not reduce worker exposure below this level will simply not be able to avail themselves of the regulatory relief offered by the action level and will therefore not be exempted from compliance with provisions triggered by the action level.

A concern raised by Charles Fryman, a CIH with the Standard Oil Company, is that detector tubes cannot be used to measure an action level (AL) set at 0.5 ppm, because colorimetric tubes "could not be used to determine exposures below the AL" [Ex. 80-89, p. 1]. OSHA's inspection data indicate that only limited reliance should be placed on detector tube data. For example, there was poor correlation between detector tube data and personal sampling results, with the detector tube sometimes indicating exposures not verified by sampling and analytical techniques more specific for formaldehyde. Thus, it would be unwise for an employer to base important decisions, such as whether or not a workplace has achieved the action level, solely on the basis of results obtained with a detector tube. The usefulness of these instruments is largely limited to leak testing or to range finding for the purpose of selecting an analytical method.

OSHA has carefully reviewed the comments received on the action level and has determined that selecting a level of one-half the final rule's PEL is appropriate. In so doing, OSHA agrees with the views expressed by Michael Larsen, who summarized the potential benefits of an 0.5 ppm action level as follows:

To minimize the regulatory impact on businesses utilizing formaldehyde materials where little health effects can be expected, I am supportive of the concept of the action level as a trigger for monitoring and medical surveillance requirements. A permissible

exposure limit of 1 part per million, 8-hour time weighted average would appropriately set the action level at .5 parts per million in air [Tr. 5/7/86, pp. 12-13].

"Emergency" is defined in the final rule as any occurrence, such as but not limited to: equipment failure, rupture of containers, or failure of control equipment that results in an uncontrolled release of a significant amount of formaldehyde. The proposal defined an emergency as "any occurrence such as but not limited to equipment failure, rupture of containers, or failure of control equipment that is likely to or does result in an unexpected significant release of formaldehyde." This change from the proposed language responds to a comment by the Medford Corporation, which stated that an emergency is an actual occurrence rather than to an event "likely to" result in an emergency [Ex. 80-37, p. 1]. OSHA agrees with this comment and has revised the definition of emergency accordingly.

Two commenters requested that "emergency" be defined in terms of a specific quantity of formaldehyde [Exs. 80-37, 80-58]. OSHA's experience, however, indicates that for most employers, emergencies are most appropriately identified in terms of specific events. For example, most workplaces design their emergency plans around various emergency events, such as fires, explosions, or rupture of a process line. Employee exposure is implicitly taken into account because it is precisely those events where employees may be endangered that constitute an emergency. In very rare cases where emergencies are frequent, the employer may find it cost-effective to continuously monitor actual exposure to determine when "significant amounts" of formaldehyde have been released. This type of activity would not be precluded by OSHA's definition.

"Employee exposure" is defined in the final rule as exposure to airborne formaldehyde which would occur without corrections for protection provided by any respirator that is in use. The definition in the final rule is merely an editorial clarification of the proposed definition. It reflects OSHA's belief that it is essential to know employee exposure levels without the use of respiratory protection to determine whether employees are being overexposed and whether additional controls are needed. OSHA received no record comments on the proposed definition of employee exposure.

"Formaldehyde" is a colorless substance with the formula HCHO and a molecular weight of 30.03. The

chemical may be present in a variety of forms in industry, including pure formaldehyde (a gas), formaldehyde solutions (e.g., formalin, which is 37-55 percent formaldehyde in water either with or without an alcohol stabilizer), and formaldehyde gas generated from solids such as paraformaldehyde and resins such as urea-formaldehyde.

The definition of formaldehyde provided in the final standard is brief:

Formaldehyde means the chemical substance, HCHO, Chemical Abstracts Service Registry No. 50-00-0.

This simple definition in the final rule is intended to convey that the standard addresses a specific chemical regardless of the form of the product in which this chemical is found. Formaldehyde may be present in simple solutions, such as formalin, or in complex mixtures, such as occur when it is used as a preservative. Formaldehyde, in its gaseous form, is released from solid materials, such as wood products, textiles, and other products that use formaldehyde-based resins, either because it is an entrapped impurity not bound up in the reaction process or it is a decomposition product. Employee exposure to formaldehyde in any of the above-mentioned circumstances is covered in this standard, since the exposure is to the chemical entity, HCHO, CAS No. 50-00-0.

To the extent that the employee inhales or has physical contact with formaldehyde, either as a gas, a liquid, or from a solid bearing formaldehyde, this exposure is covered in the standard.

Paragraph (c)—Permissible Exposure Limits (PELs)

The final rule reduces the permissible exposure limits to one part formaldehyde per million parts of air (1 ppm) as an 8-hour time-weighted average (TWA) and to two parts formaldehyde per million parts of air (2 ppm) as a 15-minute short-term exposure limit. OSHA is deleting from Table Z-2 of 29 CFR 1910.1000 the previous exposure limits of 3 ppm as a 8-hour TWA, 5 ppm as a ceiling concentration, and 10 ppm as a peak concentration. The final rule will also supersede the permissible exposure limit of 5 ppm as a ceiling concentration that is incorporated by reference in OSHA's construction standard (29 CFR 1926.55). OSHA has determined, based on the rulemaking record, that a reduction in the PELs for formaldehyde is necessary and appropriate because occupational exposure to formaldehyde at 3 ppm places employees at significant risk of mortality from cancer and exposed workers to a significant risk of skin and

respiratory irritation and sensitization. OSHA finds that these effects constitute material impairments of health within the meaning of section 6(b)(5) of the Act.

The determination that formaldehyde is a potential occupational carcinogen is based on the results in animal studies, limited evidence of formaldehyde-induced cancer in humans, and concordant evidence from short-term tests. OSHA had stated in the proposed rule that the available epidemiologic evidence, while inconclusive indicated that exposure to formaldehyde might be associated with lung cancer, brain cancer, and leukemia [50 FR 50447]. Since that time, NCI completed a cohort mortality study of formaldehyde-exposed workers showing excesses of cancer at sites in the respiratory system. This study was one of the largest epidemiological studies ever conducted and it received extensive analysis and comment during the rulemaking proceedings. In addition, recently completed studies indicated excess cancer risk in mobile home residents presumably exposed to formaldehyde [Exs. 200-3; 201-3B; 202-1, pp. 37-38]; in resin and glue workers [Ex. 202-1, pp. 30-31, 47]; and in garment industry workers [Ex. 98A]. Additional information from case-control studies indicates that exposure to formaldehyde is related to an increased risk of developing squamous cell carcinoma of the nasal passages and accessory sinuses [Exs. 173; 201-11A; 138I]. This information in humans is consistent with the results of well-designed animal studies conducted by the Chemical Industry Institute of Toxicology (CIIT) and New York University. These studies showed an increased incidence of squamous cell carcinoma of the nasal cavity in two separate strains of rats exposed to formaldehyde. Subsequent work by Tobe *et al.* [Ex. 73-146] in rats, the CIIT study in mice, and short-term tests of genotoxicity corroborate these independent findings of cancer in formaldehyde-exposed animals. Additional work by the CIIT showed that rats exposed to formaldehyde at concentrations below the 3 ppm PEL exhibited decreased mucociliary flow (*i.e.*, a breakdown of potentially protective mechanisms) and cellular alterations indicative of an early stage in a process that could lead to cancer (see Health Effects section).

In addition to determining that formaldehyde must be regulated as a potential human carcinogen, the Agency finds that a reduction in the PELs is necessary to protect employees from respiratory, eye, and skin irritation and sensitization. The corrosive irritation caused by formaldehyde has been

recognized for many years and is the principal reason that the old PEL of 3 ppm was established [Ex. 42-9]. However, evidence in the record clearly shows that many employees experience respiratory or skin irritation at formaldehyde concentrations below 3 ppm [Exs. 78-24; 78-27; 78-53; 78-76; 85-18; 85-20; 85-21; 85-23]. In addition, some employees become immunologically sensitized to formaldehyde and subsequently develop allergic skin or respiratory reactions, even when they are exposed to very low concentrations of formaldehyde. Thus, OSHA finds that formaldehyde's irritant and sensitizing effects also support the decision to reduce the PELs for formaldehyde.

OSHA relied, in part, on its cancer risk assessment (Section VI, above) in determining that a significant risk of material impairment exists at the old PEL of 3 ppm (TWA), and that reducing the PEL would substantially reduce that risk. According to that assessment, cancer risk for workers exposed to the previous PEL of 3 ppm for a working lifetime is 43.4 to 1,819 cases of respiratory system cancer per 100,000 workers. This estimate is based on application of the multistage model of carcinogenesis to a dose-response curve derived from data on induction of squamous cell carcinomas of the nasal passages in rats. These data also yield predications that reducing the 8-hour TWA PEL to 1 ppm will decrease the cancer risk to 0.6 to 264 cases of respiratory system cancer per 100,000 workers. This is a substantial decrease in the risk for respiratory system cancer. Other provisions of the standard will help reduce employee risk even further to a point that the Agency believes will approach insignificance.

OSHA has also determined that reducing the PELs will significantly reduce the associated risk from acute irritation and sensitization. Evidence reviewed by OSHA during the rulemaking proceedings indicates that, at levels permitted by the 5 ppm ceiling and 10 ppm peak concentrations, sensory irritation in humans is intolerable, causing burning and tearing of the eyes, inflammation of the moist mucous surfaces of the nose and throat, and some irritant effects in the lower respiratory system. At the 3 ppm 8-hour TWA, nearly all exposed workers experienced some irritation of the eyes, nose, and throat, with about 20 percent of the exposed workforce experiencing moderate to strong irritation with great discomfort. A 7-fold increase in the prevalence of rhinitis in exposed workers compared to controls was also

reported among workers exposed at the 3 ppm PEL [Ex. 42-130]. At the revised PELs of 1 ppm 8-hour TWA and 2 ppm STEL, evidence evaluated by OSHA indicates that there would be a substantial reduction in the severity of these effects, with the majority of formaldehyde-exposed workers who experience irritation having only transient mild effects upon exposure at the 1 ppm PEL and the 2 ppm STEL (see Section VI, Risk Assessment and Section VII, Significant Risk).

8-Hour TWA—Permissible Exposure Limit

In December 1985, OSHA proposed to reduce the 8-hour TWA PEL to either 1.0 or 1.5 ppm in response to divergent comments on the ANPR. OSHA's final determination that a 1 ppm 8-hour TWA is necessary and appropriate is based on the Agency's findings that health risks will be substantially reduced at the 1 ppm TWA concentration and that this exposure level is feasible in all sectors of industry covered by the standard. Moreover, when the reduced PELs are considered in conjunction with other provisions of the standard, such as personal protective equipment, education and training, employee exposure monitoring, medical surveillance, and housekeeping, the risk associated with formaldehyde exposure will be further reduced.

A few commenters argued that, in their opinion, no reduction in the current level of occupational exposure to formaldehyde is necessary [Exs. 80-10; 80-29; 80-69; 80-258; 80-271; 80-111A]. As the Health Effects and Significance of Risk sections amply demonstrate, exposure to formaldehyde at the old PEL of 3 ppm is associated with a significant risk of material health impairment and reduction of the PEL is thus clearly warranted.

Nearly all of the rulemaking participants who commented on the issue of a new permissible exposure limit supported the need to reduce the PELs [Exs. 72-2; 77-4; 77-10; 77-12; 77-15; 77-16; 77-17; 77-19A; alth impairment and reduction of the PEL is thus clearly warranted.

Nearly all of the rulemaking participants who commented on the issue of a new permissible exposure limit supported the need to reduce the PELs [Exs. 72-2; 77-4; 77-10; 77-12; 77-15; 77-16; 77-17; 77-19A; 12/86, pp. 185-215; Tr. 5/14/86, pp. 138, 160, 164].

In general, commenters supported one of three positions regarding the level at which to set the 8-hour TWA for formaldehyde:

- OSHA should establish a TWA of 1.5 ppm on the grounds that health risks are not significant below that level and

that many employers could not economically achieve lower levels;

- OSHA should establish a TWA of 1 ppm, which is needed to protect against irritation and represents a feasible level;

- OSHA should establish a TWA of less than 1 ppm (0.5 or 0.1 ppm), since formaldehyde is a carcinogen and must therefore be regulated to the lowest feasible level.

Many industry commenters supported OSHA's proposed alternative PEL of 1.5 ppm [Exs. 77-2; 77-14; 77-20; 77-24; 77-27; 80-6; 80-11; 80-23; 80-24; 80-26; 80-30; 80-36; 80-37; 80-38; 80-40; 80-48; 80-56; 80-60; 80-303; Tr. 5/13/86, p. 66]. For example, Ted J. Bauer, a Vice President of Medford Corporation, felt that a 1.5 ppm PEL "would provide a reasonable balance between the needs for employee safety and comfort and those for production efficiency" [Ex. 80-37, p. 1].

However, commenters supporting OSHA's alternative PEL of 1 ppm argued that 1.5 ppm was insufficiently protective [Exs. 77-11; 77-12; 77-15; 77-16; 86-1; 97; 101; Tr. 5/7/86, p. 9; Tr. 5/9/86, p. 89]. For example, Lori Abrams of the Public Citizen Health Research Group cited numerous reports showing formaldehyde to be an eye, skin, and respiratory irritant below 1.5 ppm. She also noted that, in 1976, NIOSH recommended a PEL of 1 ppm for 30 minutes based solely on formaldehyde's irritating effects [Tr. 5/9/86, p. 89]. Joseph Wolfsberger, a CIH with Monsanto, also supported a PEL of 1 ppm to reduce potential sensory irritation and pulmonary function changes [Ex. 80-58]. Other commenters, including the Formaldehyde Institute, supported a reduction in the PEL to between 1 and 2 ppm, based on evidence that exposure to formaldehyde at concentrations in the range of 0.8 to 1.2 ppm can cause irritation [Exs. 77-19A; 80-71; 164; Tr. 5/12/86, p. 185].

OSHA agrees with these commenters that a 1 ppm PEL will provide more protection from the irritant effects of formaldehyde than a 1.5 ppm PEL. For example, the subjective response study conducted by Andersen and Molhave [Ex. 42-10] clearly showed that exposure to formaldehyde at 1.6 ppm resulted in a higher discomfort score among subjects tested than did exposure at 0.83 ppm. Similar results were seen in worker populations. For example, Horvath [Ex. 66-5] reported that, among workers exposed to formaldehyde at concentrations ranging from 0.4 to 1 ppm, 27 percent experienced a burning sensation in their noses and 21 percent experienced sore throats, while corresponding prevalences were 42 and 32 percent, respectively, among workers

exposed to formaldehyde at concentrations ranging from 1 to 3 ppm.

Evidence corroborating the carcinogenic potential of formaldehyde, including cytotoxicity and the formation of benign tumors in animals exposed to formaldehyde at 2 ppm, and OSHA's risk assessment also provide evidence to reduce the PEL to 1 ppm. OSHA finds that the predicted reduction in cancer risk, along with the associated reduction in risk from acute effects, warrants reducing the PEL to 1 ppm.

A number of other commenters who supported the alternative PEL of 1.5 ppm argued that reducing the PEL to below 1.5 ppm was neither technologically nor economically feasible [Exs. 77-2; 77-20; 77-24; 80-11; 80-59; 160].

OSHA received a number of comments to the contrary, indicating that a 1 ppm PEL is attainable or has already been achieved in the affected industry sectors [Exs. 77-12; 77-15; 77-16; 77-17; 77-30; 80-11; 80-15; 80-58; 80-64; 101; 110C; 128; 175-3; Tr. 5/9/87, p. 89; Tr. 5/16/86, pp. 56-132]. These included information presented by Centaur in its feasibility study (covering wood products, foundries, and resin production) [Ex. 85-116], Dr. Melvin First of the Harvard School of Public Health (covering funeral services, foundries, textile finishing and apparel, wood products, and laboratories) [Tr. 5/16/86, pp. 56-132], and OSHA's Health Response Team in its survey of wood products facilities [Exs. 85-112; 175-3]. In addition, Larry Elliot of NIOSH testified that his survey of apparel manufacturing facilities, which included some of the smallest in the country, indicates that employee exposures are generally below 1 ppm as a TWA [Tr. 5/8/86, p. 40]. OSHA reviewed these comments and other record of evidence in making a determination that a PEL of 1 ppm as an 8-hour TWA is both technologically and economically feasible for all affected industry sectors (see the sections on Technological Feasibility in the Regulatory Impact Analysis for further discussion).

On the other hand, several commenters [Exs. 80-47; 80-50; 80-65; 80-70; 80-88; 80-257; 86-1; 89; 98; Tr. 5/6/86, p. 69; Tr. 5/8/86, p. 10; Tr. 5/14/86, p. 138] urged OSHA to adopt an 8-hour PEL below 1 ppm, arguing that it was feasible to do so and that OSHA must establish a PEL below 1 ppm to further reduce the risk from formaldehyde-related cancer and irritation. Richard Lemen of NIOSH testified at the hearing that " * * * the proposed standard is inadequate, not only to protect against carcinogenic risk, but is also inadequate protection against irritation" [Tr. 5/8/86,

p. 11]. NIOSH [Ex. 98; Tr. 5/8/86, p. 10] recommended that formaldehyde exposures be reduced to the lowest level that can be reliably detected in the workplace. In its post-hearing brief, the UAW took a similar position, arguing that OSHA must establish a PEL at the lowest feasible level, and that a TWA of 0.5 ppm could be achieved even in foundries [Ex. 173]. Daniel Teitelbaum, M.D., Director of the Denver Clinic Medical Centers testified that a PEL of 0.5 ppm would provide more health benefits than the proposed 1 ppm PEL alternative:

I think it would certainly increase the universe of people who were protected. I have had patients who could reliably detect formaldehyde in a double blinded situation at .3 [ppm]. So I think there would be some benefit to a lower PEL [Tr. 5/5/86, p. 138].

Lowell Daily and Jamie Cohen of the United Furniture Workers of America agreed that a PEL of 0.5 ppm was necessary:

If one were to consider formaldehyde only for its irritant and sensitization properties, we feel a PEL of 0.5 ppm is feasible within the furniture industry. The strong irritant properties of formaldehyde, even at low levels of exposure, have been well-documented throughout the literature. Complaints received by the UFWA Health and Safety Department from our members who are exposed to formaldehyde, include eye, nose, and throat irritations, rashes, and headaches [Ex. 80-257, p. 3].

OSHA agrees that establishing a PEL of 0.5 ppm would provide an additional margin of protection from the noncarcinogenic effects of formaldehyde, and the Agency is aware of the record evidence that suggests some employees experience irritation at exposures to formaldehyde below 1 ppm, especially if they are sensitized to formaldehyde.

OSHA acknowledges that adopting a 0.5 ppm TWA PEL rather than a 1 ppm TWA would reduce the risk of acute health effects, although it would do little to further reduce the risk of cancer which is already smaller at 1 ppm and even smaller at 1 ppm with the ancillary provisions. A 0.5 ppm PEL, however, would do little to reduce reactions to formaldehyde caused by specific sensitization, because that risk is known to persist at levels substantially below 0.5 ppm. The final rule must be viewed in its entirety, as well; the protection afforded by the 8-hour TWA is inextricably intertwined with the comprehensive program required by this standard. Based on its expertise in the field of occupational health and evidence in the record, OSHA believes that the complete standard being promulgated will provide appropriate,

feasible, administratively practicable, and comprehensive protection to employees exposed to formaldehyde.

Short-Term Exposure Limit

In addition to the 8-hour TWA PEL of 1 ppm, paragraph (c)(2) of the final rule requires that employers ensure that no employee is exposed to formaldehyde at concentrations in excess of 2 ppm measured over a 15-minute period. Although OSHA did not specifically propose a 2 ppm short-term exposure limit (STEL), the Agency stated in the preamble to the proposal [50 FR 50472] that a STEL, most likely established at 2 ppm, might be necessary to ensure that employees are not subjected to the acute adverse effects of formaldehyde exposure that would occur at the previous 5 ppm ceiling and 10 ppm peak limits and requested that commenters examine the need for a STEL [50 FR 50412]. The Agency considered a 2 ppm STEL to be feasible in the affected industry sectors [50 FR 50419].

OSHA's inclusion of a STEL in the final rule is based on evidence that short-term exposure to formaldehyde causes acute adverse effects such as sensory irritation, hyperreactive airways disease, and cytotoxic effects.

The acute effects associated with short-term exposure to formaldehyde are discussed in detail in the Health Effects section of this preamble. Based on controlled subjective sensory response studies conducted on volunteers and on studies of occupational groups, OSHA has concluded that short-term exposure to formaldehyde at concentrations exceeding 3 ppm produces nearly intolerable eye and respiratory irritation in all workers. Even at concentrations averaging 2 ppm (range 1-3), nearly all workers experience slight discomfort; (approximately 10 to 20 percent experience mild to moderate sensory irritation.) Clearly exposures above this level would be unacceptable.

Because judgments of the severity of irritant responses are subjective, and because responses are variable within a population, adequate data do not exist to permit reliable quantification of the effect that reducing the permissible exposure limits would have on the prevalence or severity of sensory irritation. However, the available evidence clearly shows that, at formaldehyde concentrations permitted by the previous 5 ppm ceiling and 10 ppm peak limits, nearly all workers would experience a degree of sensory irritation that would impair their ability to function on the job. Moreover, promulgation of the 1 ppm 8-hour TWA alone is insufficient to prevent short-

term exposure of employees to formaldehyde at concentrations in the range of 5-10 ppm; in the absence of a short-term limit, employees could be exposed to a concentration as high as 32 ppm for 15 minutes and still not exceed 1 ppm as an 8-hour TWA. OSHA has therefore concluded that short-term exposure to formaldehyde at levels permitted by the previous standard may cause material impairment of health and functional capacity, and that by reducing the short-term limit to 2 ppm, the majority of workers will be protected against such effects (see Section VII, Significant Risk).

In addition to reducing the prevalence and severity of irritant responses to formaldehyde, a 2 ppm STEL will reduce the prevalence of occupationally induced asthma and reactive airways disease. At the informal hearing, Dr. Teitelbaum testified that new cases of reactive airways disease will continue to develop among formaldehyde-exposed workers unless a STEL is imposed:

I have seen such short-term exposures in health care situations, in a number of glueing operations * * *. Based on the work which Brooks and Bernstein and Weis have recently published demonstrating persistent reactive airways dysfunction syndrome following short-term exposures to very irritating materials, it would be my view that these are potentially serious problems * * *. It is appropriate to have a short-term exposure limit * * * certainly not above 2 or 3 ppm and * * * without that, we are going to see continuing reactive airways disease, as well as of course the acute bronchiolitis * * * doesn't leave a permanent injury [Tr. 5/5/86, p. 133].

In addition, research conducted by the CIIT [Exs. 70-23; 73-81F] and a study by Wilmer and co-workers [Ex. 85-107] have shown that exposure concentration is a more important factor for formaldehyde-induced cytotoxicity than is cumulative dose. A single 6-hour exposure to 6 ppm or 15 ppm was sufficient to produce cytotoxicity in the nasal passages of rats; rats exposed to a single 6-hour exposure of 0.5 ppm or 2 ppm did not exhibit any cellular changes in the nasal epithelium [Ex. 73-81F]. NIOSH has concluded that the Wilmer *et al.* study provides "strong evidence in support of a carcinogenesis mechanism for formaldehyde involving cell killing and cell proliferation" [Ex. 98, pp. 7-8]. Similar pathological findings were reported in the chronic CIIT study from interim and unscheduled sacrifices of mice and rats [see Ex. 42-131]. Thus, OSHA believes that the appearance of cytotoxic changes, even following short-term exposure to formaldehyde, is indicative of an increased risk of

developing cancer. Therefore, reducing the STEL to 2 ppm will further limit formaldehyde-induced cytotoxicity, thus reducing the probability of developing cancer.

The view that a revised short-term limit will reduce the potential for the formation of precancerous lesions was supported by NIOSH [Ex. 98], Michael Larsen [Tr. 5/7/86, pp. 11-12], Robin Whyatt of the National Resources Defense Council (NRDC) [Tr. 5/15/86, p. 10], and Dr. Franklin Mier of the UAW [Ex. 173, p. 13]. NIOSH stated that the data indicating that cytotoxicity is concentration dependent " * * support the need to reduce formaldehyde exposure concentration to the fullest extent feasible, particularly by reduction of short-term high exposures" [Ex. 98, p. 9].

Other commenters pointed out that a STEL was needed to prevent extremely high exposures from occurring in work operations where formaldehyde's use is characterized by short-term exposures to formaldehyde. For example, Michael Larsen noted in his post-hearing comments that pathologists, photographic film developers, embalmers, biology teachers, anatomists, tissue preparers, and workers in operations using formaldehyde-containing adhesives and glues have only intermittent exposure to formaldehyde [Ex. 135, p. 2].

The intermittent nature of exposure to formaldehyde among hospital workers was also discussed by James Notarianni, Technical Services Coordinator for Gas Monitoring and Analysis, Inc.

* * * a revocation of the STEL's for formaldehyde would not be in the best interest of employee health, particularly in the hospital laboratory environment. It has been my experience that the majority of occupational exposure to formaldehyde in the hospital laboratory environment is of a short-term nature, and that 8-hour TWA exposure assessments only may not adequately outline potential employee overexposure. Specific laboratory procedures involved with gross specimen preparation, specimen disposal, formalin mixing, etc. pose a substantial threat of high-level, short-term exposure to formaldehyde, both as an eye and respiratory system irritant, and also in terms (as is noted in the proposed rule) of other more serious acute health risks. If a STEL is not instituted, these risks may go unassessed by 8-hour TWA monitoring only [Ex. 80-260, p. 1].

Clare Sullivan of the UPIU testified that short-term exposures ranging from 4 to 10 ppm have been reported in the coatings preparation areas in papermills and in specialty and corrugated paper operations [Tr. 5/15/85, pp. 6-7]. She also testified that UPIU members have reported symptoms such as nausea,

nosebleeds, and upper respiratory distress following short-term exposures of this magnitude. Scott Schneider of the United Brotherhood of Carpenters urged OSHA to adopt a STEL because of the need to limit intermittent exposures to formaldehyde that occur in the construction industry [Tr. 5/14/86, p. 159].

After reviewing this testimony and other evidence in the record, OSHA is convinced of the need to include a STEL in the final rule for formaldehyde, since many work operations are characterized by intermittent exposures to formaldehyde, rather than by relatively constant levels of exposure. In situations where there is the potential for intermittent exposure during certain work operations, imposing a limit on the 8-hour TWA exposure alone would not adequately ensure the protection of employee health and functional capacity. To the extent that employee exposures in a workplace are characterized by constant, low level exposure to formaldehyde, the STEL should present no additional burden.

The vast majority of rulemaking participants who addressed the issue of a STEL believed that 2 ppm was appropriate to protect workers against irritant effects, although opinions differed as to the duration over which short-term exposures should be monitored. These commenters included the Formaldehyde Institute [Ex. 80-71], the American Apparel Manufacturers Association (AAMA) [Ex. 77-2], the Hardwood Plywood Manufacturers Association (HPMA) [Ex. 77-18; Tr. 5/13/86, p. 137], the National Cotton Council [Exs. 77-20, 80-59], the American Textile Manufacturers Institute (ATMI) [Exs. 77-27, 80-303], the International Chemical Workers Union [Ex. 80-50], the Society of the Plastic Industry, Inc. (SPI) [Ex. 80-80], Public Citizen Health Research Group [Tr. 5/9/86, p. 94], and several companies that produce or use formaldehyde-containing products [Exs. 77-10; 77-15; 77-16; 77-17; 77-23; 80-26; 80-38; 80-48; 80-58; 80-64; 80-77; 80-78]. The need to limit short-term exposures to formaldehyde has been recognized by many employers, as evidenced by the number who have adopted a 2 ppm internal short-term limit [Exs. 77-15; 77-16; 77-17; 80-58; 80-64; 80-85].

Among the commenters who supported a 2 ppm STEL, opinion was divided on whether exposures should be averaged over a 15-minute exposure period [Exs. 77-16; 80-64; 80-48; 80-78; 80-272] or a 30-minute exposure period [Exs. 77-10; 77-12; 77-15; 77-17; 77-18; 77-27; 80-38; 80-56; 80-59; 80-71; 80-303; Tr. 5/13/86, p. 137; Tr. 5/7/86 p. 170].

Commenters suggesting a 30-minute STEL expressed concern over the accuracy of monitoring results when a 15-minute sampling period is used. For example, William Groah of the HPMA commented that a sampling period of 30-minutes would be

sufficiently long to characterize worker exposure and still provide values that are within the range of accuracy for currently used analytical methods when the observed levels are something less than [sic] the allowable STEL [Ex. 77-18, p. 1].

Peter Breyse also favored a 30-minute STEL because it might permit the use of passive dosimeters to monitor short-term exposures [Tr. 5/7/86, pp. 170-171]. As discussed in the exposure monitoring section of this preamble, a number of methods are available that can be used to monitor 15-minute average short-term exposures for formaldehyde within the limits of accuracy required by the final rule. OSHA finds that the promulgation of a 15-minute STEL will not prevent employers from using simplified methods for monitoring short-term exposures to formaldehyde.

OSHA's selection of a 15-minute rather than 30-minute STEL in the final rule is based on the Agency's findings that at 2 ppm 15-minute STEL is technologically feasible (see Section VIII of this Preamble) and that a 15-minute STEL will be more protective against acute effects than a 30-minute STEL. Because the short-term limit for formaldehyde is expressed as an integrated, or average, exposure over a given period of time, a STEL averaged over 15 minutes will provide little opportunity for workers to be exposed to higher concentrations of formaldehyde over a shorter period of time. In contrast, a 2 ppm 30-minute STEL might permit workers to be exposed for brief periods of time (*i.e.*, 5 or 10 minutes) to concentrations of formaldehyde that are intolerably irritating. Promulgating a 15-minute STEL will provide an additional measure of protection against such an occurrence.

In addition, STELs have traditionally been established by OSHA, as well as by the American Conference of Governmental Industrial Hygienists (ACGIH), as 15-minute average exposures unless a different period is warranted by the observed biological effects. In the case of formaldehyde, there is no evidence which justifies a 30-minute STEL. OSHA believes that the more conventional 15-minute STEL period is to be preferred in the absence of a compelling reason to the contrary.

A number of rulemaking participants urged OSHA to promulgate a STEL of 1.5 ppm or 1 ppm [Exs. 80-47; 80-65; 80-88; Tr. 5/7/86, p. 38; Tr. 5/8/86, p. 131; Tr. 5/15/86, p. 107] " * * * to be more protective against the irritative effects of formaldehyde than a 2 ppm short-term exposure limit" [Tr. 5/7/86, p. 38]. The other commenters who supported a lower STEL recommended that OSHA adopt a 1 ppm STEL based on NIOSH's 1976 recommendation that exposures to formaldehyde not exceed 1 ppm over 30 minutes to protect against irritant effects, particularly among those few workers who might experience a moderate level of discomfort at formaldehyde concentrations of 1 ppm.

OSHA is aware, from its review of the formaldehyde literature, that some workers will experience discomfort when they are exposed to formaldehyde at concentrations below 1 ppm; these employees may react adversely to low concentrations of formaldehyde either because of intrinsic hypersusceptibility to irritants or because they have become sensitized to formaldehyde as a result of excessive exposures in the past. To adopt an exposure limit that ensures that no employees will experience even mild irritation would require that short-term exposures never exceed levels far lower even than 1 ppm (*i.e.*, 0.1 or 0.2 ppm), levels that OSHA has determined could not be technologically achieved in most formaldehyde-using facilities.

OSHA's intent in issuing a 2 ppm STEL is to ensure that most employees are not exposed to levels of formaldehyde that will cause marked sensory effects of sufficient severity to compromise their ability to perform their work in a safe manner. The studies reviewed by OSHA (see Health Effects and Significant Risk sections of this preamble) as well as the experience of companies that have adopted a 2 ppm internal short-term limit indicate that the vast majority of workers will not experience significant acute effects if exposures are maintained below a 2 ppm STEL. Moreover, other provisions in the standard, such as medical surveillance, protective equipment, employee information and training, hygiene facilities, and housekeeping, may afford some degree of protection for the small number of hypersensitive workers. As discussed earlier in this section, the 1 ppm 8-hour TWA alone is insufficient to ensure that employees are protected from these acute effects. Thus, OSHA finds that, by promulgating a 2 ppm 15-minute STEL, in addition to the TWA, the Agency has, to the extent feasible, ensured that employees will be protected from experiencing health- and

work-impairing formaldehyde exposures in their workplaces.

Alternative Regulations

Evidence in the record indicates that it is feasible for many industry sectors to achieve exposure levels lower than the TWA that is being adopted. Since there is some residual risk at 1 ppm, OSHA explored the possibility of setting different PELs for various sectors of the industry based on feasibility for each sector rather than basing this determination on feasibility in all formaldehyde-handling industries as a whole.

Clearly, a PEL could not be set below 0.1 ppm because of the need to be able to distinguish occupational exposure from environmental, or ambient levels. Based on record evidence, it appears possible that a PEL of 0.5 ppm is the limit of feasibility in many industries, and for a few where point source emissions are difficult and expensive to control, a PEL of 1 ppm would be required.

Review of the information on the various industry sectors, however, indicated that some of them are not readily distinguished. For example, some furniture manufacturers make their own wood products; others do not. Wood products producers may manufacture their own boards or they may finish imported boards. Exposures in foundries depend on the type of process used; some use no formaldehyde at all and others have some of the highest exposures seen in any industry. Therefore setting industry-specific PELs is not practical in this instance, nor does OSHA believe that it is a preferred option for protecting worker health.

Substantial incentives have been incorporated into the standard to encourage each employer to lower airborne exposures in individual plants to the extent feasible. OSHA believes that setting a standard that requires no action on the part of an employer who maintains a workplace with exposures near ambient levels and free of dermal hazards associated with formaldehyde; limited actions on the part of an employer who maintains airborne levels below 0.5 ppm but above demonstrable levels; and more extensive protection, including annual training, exposure monitoring, and medical surveillance for employers who maintain exposure levels below 1 ppm but above 0.5 ppm is the most cost-effective approach that will provide the greatest protection to formaldehyde workers. This approach to regulation is potentially capable of affording greater protection to workers in some industry sectors than they would obtain if sector-specific PELs

were set. Since individual employers at each plant will have the incentive to lower airborne levels based on their own capabilities, many workers in industry sectors where feasibility is an issue for some plants should have lower airborne exposures than would be likely if a sector-specific PEL without incentives were promulgated.

Some commenters argued that eye, nose, and throat irritation provide workers with an adequate warning to avoid being exposed to formaldehyde at concentrations that have caused tumorigenic responses in rats [Tr. May 12, 1986, p. 96]. While OSHA agrees that formaldehyde's irritant properties may have helped limit the exposures of many workers in the past, frequently to levels below the existing OSHA standard, OSHA also believes that this observation does not displace the employer's obligation to maintain a safe and healthful workplace free of recognized hazards, including irritation. Nor does this argument alter OSHA's determination that the revised regulation is necessary to protect workers' health from significant risks, including that of cancer.

Paragraph (d)—Exposure Monitoring

Section 6(b)(7) of the Act mandates that standards shall, where appropriate, " * * * provide for monitoring or measuring [of] employee exposures at such locations and intervals, and in such [a] manner as may be necessary for the protection of employees." Accordingly, OSHA has included requirements for employee exposure monitoring in the final rule. OSHA believes that regular monitoring of employee exposures is an essential component of occupational health programs that provides important information to employers on the effectiveness of their engineering controls and work practices. In addition, monitoring tells the employer whether his or her obligation to maintain employee exposures at or below the PELs is being met.

Exposure monitoring has been required in many of OSHA's previous substance-specific health standards (see Vinyl Chloride, 29 CFR 1910.1017; Inorganic Arsenic, 29 CFR 1910.1018; Lead, 29 CFR 1910.1025; Cotton Dust, 29 CFR 1910.1043; DBCP, 29 CFR 1910.1044; Acrylonitrile, 29 CFR 1910.1045; Ethylene Oxide, 29 CFR 1910.1047; Benzene, 29 CFR 1910.1028). The monitoring requirements of this final rule contain many of the same elements as monitoring requirements in other OSHA health standards, including provisions for initial and periodic monitoring; the use of representative sampling

strategies; the use of objective data in lieu of initial monitoring; termination of monitoring; precision and accuracy of monitoring methods; and employee observation and notification of required monitoring results. In some instances, the regulatory text differs from that of other standards in order to clearly spell out acceptable monitoring techniques specific to formaldehyde. Changes in wording or format do not necessarily signal a change in regulatory intent between regulations, especially when no such change is noted in the preamble. Rather, changes of this nature should be interpreted in the context of the purpose of the regulatory provision.

The monitoring provisions in the final rule have been amended from those in the proposal to include requirements for monitoring short-term employee exposures to formaldehyde. This change reflects OSHA's determination that a short-term exposure limit is necessary to protect employees from the adverse health effects of formaldehyde exposure and it is necessary to require the employer to assure that the STEL has not been exceeded. Accordingly, the final standard includes both an action level and a 15-minute STEL as triggers for the initial monitoring and frequency of monitoring requirements.

Three additional changes from the proposed rule have been made: information on how to conduct a representative sampling strategy has been expanded, but this information is now completely nonmandatory. A method for selecting employees to be monitored is presented in Appendix B. Second, the requirement to increase periodic monitoring if the PEL is exceeded has been deleted since OSHA did not find any evidence that this would actually lead to a reduction in employee exposure. Third, because the product manufacturer is not required to provide a material safety data sheet (MSDS) to purchasers unless it is suspected that the product is "hazardous", employers who would be unaware of the presence of trace amounts of formaldehyde in products are exempted from monitoring requirements.

Objective Data

Paragraph (d)(1) of the final rule requires that each employer covered by this standard monitor his or her employees to evaluate their exposure to formaldehyde. Paragraph (d)(1)(ii)(B) relieves the employer of this monitoring burden if objective data show that the use of formaldehyde or formaldehyde-generating products cannot, under foreseeable conditions of use, release formaldehyde into the workplace air in

concentrations at or above the action level of 0.5 ppm or the STEL of 2 ppm. The objective data provision is similar to the proposed provision, except that the phrase "formaldehyde-generating products" is used in place of "formaldehyde products" to clarify that only those products capable of releasing formaldehyde and thus presenting a hazard are included in the standard. This provision is included to minimize the costs of initial monitoring in circumstances where insignificant amounts of formaldehyde are present in the workplace and where the risk of exposure to formaldehyde is small. Employers can use data on physical properties, combined with information as to room dimensions, air exchange rates, and other pertinent data, including, for example, information on work practices, to estimate the maximum exposures that could be anticipated in the workplace. Relying on such an approach to estimate worker exposures from objective data requires the use of safety factors to account for uneven dispersion of formaldehyde vapor in the air and the proximity of workers to the emissions sources [Ex. 73-176]. Objective data could also include historical data on employee exposures, area monitoring conducted to determine ambient formaldehyde levels and emissions from sources of formaldehyde releases, or carefully evaluated monitoring conducted for other than a full shift or 15-minute period.

A number of commenters supported inclusion of a provision allowing the use of objective data in the monitoring requirements for the final rule [Exs. 80-56, 80-86, 80-89, 85-111C]. For example, Charles E. Fryman, of Standard Oil Company, suggested that "engineering studies and source sampling" can also be used as objective data that document potential exposures to formaldehyde, and that using this approach would reduce monitoring costs for many workplaces. He elaborated as follows:

As recommended by the American Conference of Governmental Industrial Hygienists in their publication *Industrial Ventilation*, there are situations where simple calculations can be used to estimate workplace concentrations of gaseous contaminants. Given gaseous formaldehyde emission rates in a closed area, such as a room, and knowing the general ventilation rate for the closed area, the concentration of formaldehyde can be estimated [Ex. 80-89, p. 2].

Other commenters expressed reservations about the objective data exclusion for monitoring. Richard Lemen of NIOSH suggested that OSHA should clarify the definition and meaning of the

term "objective data," (which has been done in Appendix B) and that OSHA should indicate "what constitutes sufficient evidence of compliance with the [objective data provision]" [Tr. 5/8/86, p. 18]. In a similar vein, Michael Larsen testified that:

Employers using objective data to exempt themselves from monitoring requirements must do so using the utmost . . . discretion. Many industries may justifiably feel that their product has a low potential for release of formaldehyde. Conditions downstream from the manufacturing process, however, may be such that a significant formaldehyde exposure could be experienced due to circumstances beyond the control of the manufacturer. For instance, consumer articles impregnated with a formaldehyde resin may hold little potential for releasing measurable amounts in a retail environment. The warehouse where the articles are stored, however, may demonstrate sharply elevated levels [Tr. 5/7/86, p. 13].

Several participants strongly objected to the inclusion of an objective data exemption for monitoring on the grounds that objective data cannot account for all of the complex parameters and factors that determine the magnitude of employee exposures to formaldehyde, and that employer judgments in estimating exposures may be inaccurate [Exs. 80-38; 80-65; 80-70; 80-257; 98; 106; 113; 135; 176; Tr. 5/8/86, p. 18; Tr. 5/7/86, p. 26; Tr. 5/14/86, p. 133]. These commenters urged OSHA either to delete the objective data provision or to clarify the kinds of data that can serve as objective data for the monitoring exemption. For example, Scott Schneider testified that:

Exposures may vary based on temperature and humidity of the workplace, work practices used by an individual, general and local exhaust ventilation used, the age and maintenance history of the machine being used and the ventilation system * * * and many other variables. OSHA needs to set some guidelines so that employers cannot use this exception as a huge loophole to escape the requirements of the standard [Tr. 5/14/86, p. 133].

OSHA recognizes that many workplace factors must be taken into account by employers relying on objective data (see 50 FR 50473). When workplace conditions such as those described by Mr. Larsen exist, employee exposures above the action level and STEL may result even from the storage or handling of products that contain relatively small amounts of formaldehyde.

In retaining the objective data requirement, OSHA does not intend that employers engage in complex modeling exercises as a substitute for employee exposure monitoring, and the Agency

recognizes that, in workplaces where many complex factors must be considered to use objective data, a high degree of uncertainty will be associated with trying to assess employee exposures from objective data. In these instances, employers should conduct exposure monitoring instead of relying on objective data so that they can have confidence that they are in compliance with the standard's provisions.

Moreover, in workplaces where many complex factors combine to influence employee exposures to formaldehyde, employers may find it easier, more useful, and less costly to monitor rather than to try to evaluate employee exposures through the generation and evaluation of objective data.

For example, compliance with the HUD product standard limiting formaldehyde emission rates should not be used by certain employers as objective data unless additional monitoring is performed to prove that the action level will not be exceeded, despite comments suggesting this approach [Exs. 80-38; 80-86; 80-257; Tr. 5/14/86, p. 132]. The HUD tests alone may not be relevant as objective data because they apply to emissions in a finished building and may not give an accurate assessment if such materials are being sawed or sanded.

Jerry C. Connors, President of the Manufactured Housing Institute (MHI), felt that the manufactured housing industry is an "ideal candidate" for the objective data exclusion. He elaborated that:

Our supplier, the wood products industry, has . . . gathered objective data to ensure its products are complying with the HUD product standards. The HUD standards call for emission levels that do not exceed 0.2 ppm for plywood and 0.3 ppm for particleboard. The HUD target level for new manufactured homes is an ambient level of 0.4 ppm. One of the principal industries involved, particleboard, has adopted voluntary industry standards for *all* particleboard products that match the HUD particleboard standard. Another, the hardwood plywood industry, is in the process of adopting an industry-wide voluntary standard similar to HUD's plywood standard. The net impact of these standards is to ensure that currently over 80 percent of all particleboard is produced to the HUD standard, even though only a relatively small portion of the total is used in manufactured home production [Ex. 80-86, p. 11].

However, the MHI also collected employee exposure data within their industry sector [Ex. 80-86, p. 8] so that some correlation between the HUD emission test data and expected exposures can be made. Of 73 samples taken at eight plants, all but three showed 8-hour TWA exposure levels

below 0.3 ppm. Most of these samples were taken at operations where large amounts of particleboard were present. The highest exposure level reported (0.72 ppm) was taken in a drapery sewing department; the next two highest exposures (0.63 and 0.48 ppm) were detected in mill rooms where dust from pressed-wood products was present. Thus, it appears that under certain circumstances, while the HUD certification provided useful data for assessing employee exposure, merely meeting the HUD product standard might not ensure employee exposure below the action level.

On the other hand, data submitted by the Weyerhaeuser Company indicated that employee exposure in the wood products distribution centers are likely to be below the action level. In addition, sampling showed that ambient formaldehyde concentrations in warehouses rarely exceeded 0.1 ppm and never exceeded 0.14 ppm [Ex. 80-38, Appendix B].

Some commenters strongly objected to any use of HUD data for assessing employee exposure. Scott Schneider of the Carpenters and Joiners testified that:

We fail to see the relevance of the HUD standard with regard to occupational exposures in the wood products industry. The exposures of . . . workers sanding or cutting particleboard bear little relationship to the amount of formaldehyde off-gassing from the board. The same is true for workers applying formaldehyde resins to a board or running a veneer press. There is no way to predict these exposures based on the HUD standard [Tr. 5/14/86, p. 132].

Similarly, Lowell Daily and Jamie Cohen of the United Furniture Workers of America stated:

The UFWA strongly objects to * * * [the objective data] proposal. It is our belief that too many workers will be at greater risks of exposure if downstream employers are allowed to use so called "objective data," such as HUD regulations, to make a determination that monitoring is unnecessary. Relying on this type of "objective data" does not take into account the amount of respirable wood dust containing formaldehyde, which is inhaled by machine operators. Monitoring is the best assurance that the employers and employees will be informed of the concentrations of formaldehyde. Based on the [UFWA] survey results, it is clear that most employers do not know the levels of formaldehyde in their plant. We believe that the proposed formaldehyde standard should contain provisions which require all employers who use formaldehyde containing materials to monitor employee's exposure to formaldehyde [Ex. 80-257, pp. 4-5].

Using the objective data provision in the manner described by Mr. Schneider, Mr. Daily, and Ms. Cohen is not

consistent with the standard's intent. HUD standards for wood products specifically require formaldehyde offgassing rates which are designed to limit the potential for significant airborne concentrations of formaldehyde in homes made from such products. HUD product standards should not be used as a sole justification for failure to monitor machine operators exposed to respirable wood dust containing formaldehyde; the exposure data submitted by MHI confirm this. However, an employer with a wood products warehouse facility might reasonably use a combination of data, such as the wood emissions data and information on air exchange rates in the facility, to show that employee exposures in the warehouse cannot exceed the action level or STEL under the foreseeable conditions of use.

Exemption from Monitoring for Trivial Amounts

In the final rule, OSHA is permitting one additional exemption from the requirement to monitor exposure. According to paragraph (d)(1)(ii)(A), the employer need not initiate exposure monitoring unless there is a formaldehyde hazard as defined in paragraph m of this standard or there are employee health complaints possibly associated with formaldehyde exposure. This exemption addresses the problem that very small amounts of formaldehyde are offgassed from many end-use products, such as drapes, pressed wood furniture, sofas, rugs, and paper products.

When these products release only small amounts of formaldehyde, such that exposure in downstream industries resulting from all of the formaldehyde-bearing or releasing products present under normal conditions of use is not expected to exceed 0.1 ppm, the manufacturer need not label the product nor provide a material safety sheet (MSDS). Under such circumstances, employers will not normally be expected to monitor for formaldehyde exposure in the workplace. Indeed, such employers will frequently be unaware that trace amounts of formaldehyde are present.

However, there are some circumstances where the concentration of formaldehyde in the atmosphere might increase to levels higher than the manufacturer of the product could anticipate either because the downstream user is not using the product in a "normal" manner or because much greater number of products releasing formaldehyde are present than the manufacturer could anticipate. The typical situation where

this condition develops is in newly renovated offices where many new materials may be offgassing a maximum amount of formaldehyde at the same time. Consequently, if employees have medically related complaints that could possibly be related to formaldehyde exposure, the employer will have to monitor for formaldehyde despite any exemption given otherwise. Once the complaints have been resolved and any formaldehyde exposure abated, the employer would no longer be required to continue monitoring.

This exemption is intended to prevent employers from being jeopardized by a potential citation for failure to monitor employee exposure when they could not possibly know that formaldehyde is present. "Sick building syndrome", however, is well-known as is the suspicion that formaldehyde may be one of the contributors to this disease, and OSHA expects employers to recognize this as a special circumstance that may require exposure monitoring.

Initial Monitoring

The final rule requires that employers conduct initial monitoring to identify all employees who are exposed to formaldehyde at or above the action level of STEL. This sampling need not include personal sampling of each individual employee because employers may choose to monitor on a representative basis. Initial monitoring must be repeated whenever there have been any changes in the workplace that could lead to new or additional exposures to employees (*i.e.*, when the sampling strategy is no longer representative). In addition, employers must assure, if representative sampling is used, that measurements representative of the employee's work shift or short-term exposure to formaldehyde and of each job classification in each work area are taken. This approach helps to limit the number of samples necessary to represent the exposures of a group of employees working at the same task.

Initial monitoring in the final rule has been expanded from the proposal to require employers to identify and monitor employees who are exposed to formaldehyde in excess of the 2 ppm STEL in addition to monitoring employees exposed above the action level. This change in monitoring requirements is necessary and appropriate so that the employer can assure that the STEL as well as the TWA has not been exceeded.

Strategy for Initial Monitoring

In the proposal, OSHA described in detail how to identify employees whose

exposures to formaldehyde should be monitored. Since the purpose of the monitoring program is to enable the employer to determine the exposure of each employee exposed to formaldehyde above the action level or STEL, the employer must first establish where exposure to formaldehyde occurs. To identify initially the operations where employee exposure may need to be monitored, the employer should consider at least the following elements: the potential that operations or processes at the worksite will release formaldehyde into the work environment; evidence that employees have complained of signs of symptoms indicative of formaldehyde exposure; and each employee's distance from sources of formaldehyde emissions, the employee's mobility, air movement patterns, and differences in work habits of the employees.

The employer must then devise a sampling strategy that will ensure identification of all employees exposed above the action level of STEL. The sampling strategy must also be sensitive enough to detect changes in exposure or trends that occur over time. A detailed description of how to identify employees for monitoring and a cost-effective sampling strategy for monitoring are described in Appendix B.

To determine if the action level or STEL is actually exceeded, employers who cannot make a determination based on objective data must conduct exposure monitoring. The employer may measure the exposure of all employees potentially exposed to formaldehyde. The employer may also develop a sampling strategy to measure exposures of representative employees. In general, however, the most efficient sampling strategy identifies and measures employees presumed to have the highest exposure potential. The object of selecting maximum risk persons is to determine if the measured exposure of any employee is above the action level or STEL. If the exposure of the most heavily exposed employee within a given group (based on work tasks or location of the work station) does not exceed the action level or STEL, then other employees in the work area are probably not exposed above the action level or STEL and no further measurements need to be done until conditions change to the extent that the validity of the measurement can no longer be assured. When conditions change, the initial monitoring procedure begins anew.

Samples collected to determine compliance with the STEL are handled in the same manner as those for the TWA exposure assessment, with two

exceptions. First, measurements taken for the purpose of determining employees' STEL exposures are taken during periods of maximum expected airborne concentrations of formaldehyde. Second, samples are usually collected in a nonrandom fashion, taking into account all available knowledge of the individual, the work station, the job being performed, process variables, and relevant environmental conditions (*e.g.*, heat, humidity).

There are situations where employee exposure appears to be constant throughout the workshift. In this case, measurement of the short-term exposure through nonrandom sampling may be impossible. However, OSHA believes that these employers will be able to use full-shift exposure monitoring data coupled with the objective data provision to demonstrate that actual monitoring for the STEL is unnecessary.

This exposure survey approach, which was developed by Leidel, Busch, and Lynch and described in NIOSH publication 77-173, *Occupational Exposure Sampling Strategy*, was recognized in the rulemaking record as being reasonable and appropriate. For example, David P. Lewis, a CIH with Weyerhaeuser Company, supported OSHA's proposed monitoring strategy, stating that it "helps to limit the number of samples that have to be collected and is critical to practical worker exposure evaluations" [Ex. 80-38, p. 7]. Mr. Fred Bowditch, Vice President, Motor Vehicle Manufacturers Association, reported from his survey of 10 motor vehicle foundries that "the sampling strategy used to determine which employees should be monitored for formaldehyde exposures was not appreciably different among the * * * [facilities surveyed]. Sampling strategies * * * were in large part a result of the industrial hygienist determining where the exposures were most likely to occur" [Ex. 200-8, p. 1 of Enclosure 1].

Use of the Action Level Trigger for Initial Monitoring

A number of commenters supported OSHA's proposed use of the action level to trigger initial monitoring [Exs. 77-11; 77-24; 77-37]. Dr. Millar, Director of NIOSH, commented that

The action level is an effective means by which the employer can monitor the effectiveness of existing controls and, in the event of exposures beyond the action level concentration, take remedial action [Ex. 77-11, p. 1].

Lloyd F. Wood of Occidental Chemical Corporation agreed, stating that use of the action level for the monitoring provisions would make the

formaldehyde standard more cost effective [Ex. 77-37, p. 1]. [See also Ex. 77-24, p. 7.]

Other commenters disagreed with OSHA's proposed action level trigger for initial monitoring on the grounds that initial monitoring should be triggered by the PEL [Exs. 77-14; 80-59]. P.J. Wakelyn of the National Cotton Council of America noted that "the requirement for initial monitoring should be to demonstrate adequately by an appropriate method * * * that the workplace is below the PEL" [Ex. 80-59, p. 6].

OSHA agrees with Dr. Wakelyn that the intent of monitoring is to identify persons who, at times, may be exposed above the PEL; however, formaldehyde exposures would be expected to vary from day to day depending on process variables and environmental conditions, so that it is not appropriate to begin monitoring only when it is known that a single daily exposure is exactly at the PEL. Instead, monitoring should commence when employees are identified as having exposures that may be significant, that is, at or above the action level. Such exposures may be approaching the PEL and they must be carefully evaluated over a period of time. By taking this approach, employers can be reasonably confident that they have identified all high-risk employees. Therefore, OSHA has retained the requirement that employers conduct initial monitoring for all employees who are potentially exposed at or above the action level.

Periodic Monitoring

Once an employer has identified employees who are potentially exposed to formaldehyde and have determined their exposures, the results of the employee monitoring will establish if the employer must continue to monitor the employees' exposure to formaldehyde. If initial monitoring reveals that employee exposure is below the action level or the STEL, no further monitoring is required until conditions change sufficiently so that exposure may have increased to above one of the triggers. If the employees' exposures are above the action level, the employer must conduct additional exposure monitoring within 6 months after initial monitoring and every 6 months thereafter so long as exposures remain at or above these levels. The employer must also take such measurements as are necessary to assure compliance with the STEL; these measurements must be conducted at least once a year under worst conditions.

As explained in the preamble to the proposed rule, the primary purpose of

periodic monitoring is the observation of trends or systematic changes in exposure levels (see 50 FR 50473-50474, which is hereby incorporated by reference insofar as it is consistent with the final rule). Periodic measurements are one of the most informative ways of detecting hazardous shifts in exposure concentrations, an indicator that engineering controls are not working properly or that good work practices are not being followed.

Some commenters objected to the proposed requirement for periodic monitoring of employee exposures where exposures exceed the action level on the ground that the health risks of formaldehyde exposure are not significant below the PEL [Exs. 77-10; 77-33; 80-58; 80-61; 80-68; 80-71; 80-303] and that the frequency of monitoring is best left to the judgment of health care professionals or employers. On the other hand, other commenters believed that periodic monitoring should be conducted if employee exposures exceed the action level [Exs. 77-11; 77-37; 77-42; 77-93].

OSHA's intent in requiring periodic monitoring when employee exposures meet or exceed the action level is to ensure that employees are not, in fact, being exposed to formaldehyde over the 1 ppm PEL and that employers are kept apprised of the effectiveness of their engineering and work practice controls. As discussed previously, once employee exposures exceed the action level, employers cannot be confident that employees are never exposed above the 1 ppm PEL. Thus, OSHA believes it is important, if employee exposures are at or above the action level, for employers to continue to monitor the exposures of their employees to assure themselves that their employees are not overexposed. In addition, adverse health effects have been detected at exposures between 0.5 and 1 ppm.

Two rulemaking participants [Exs. 77-10, 80-58] maintained that it is unnecessary to conduct periodic monitoring if employee exposures are below the PELs, since employees can detect the odor of formaldehyde. OSHA believes that, while detection of odor might indicate a problem, probably indicating a need to examine whether or not the STEL is being exceeded, sensory detection of airborne formaldehyde by workers is an unreliable indicator of exposure levels, especially for TWAs. At the hearing, Mr. Larsen pointed out that the "perception of the irritative effect [of formaldehyde] diminishes over time." He concluded that "the nose is an exceedingly poor tool for industrial hygiene evaluation" [Tr. 5/7/86, pp. 22-23]. Indeed, the odor threshold for many

persons is above the 0.5 ppm action level. Thus, OSHA concludes that sensory detection of formaldehyde cannot be relied on to determine whether employees are exposed at or above the action level, and the Agency reaffirms the necessity of conducting periodic employee exposure monitoring to accurately determine the levels of formaldehyde present in the workplace.

Periodic monitoring must be conducted with sufficient frequency to assure that a true measure of existing conditions is made. Evidence in OSHA's record indicates that substantial shifts in exposure potential occur in many industry sectors between winter and summer. For this reason, the minimum requirements for sampling for compliance with the TWA are established as every 6 months and employers who have workplaces where initial monitoring has indicated exposures above the action level are not permitted to terminate periodic monitoring until two consecutive samples have been collected. In contrast, noncompliance with the STEL is more likely to be related to a poor work practice or inadequate control devices than to environmental conditions, so that a sampling strategy that measures for compliance with the STEL can be performed annually in many workplaces. It is, however, critical that this measurement be taken under "worst case" conditions to be valid measures.

Although the Agency had proposed to require more frequent monitoring if the TWA is exceeded, OSHA now concludes, upon review of the record on formaldehyde and consideration of sampling strategies in other health standards, that no particular goal would be achieved by increasing monitoring once the TWA is exceeded if the situation is a stable one, but simply one beyond the employer's present ability to abate. Because of the substantial incentives to lower employee exposure, however, the employer whose workplace has exceeded a PEL may wish to conduct more frequent monitoring to determine if the condition has been abated by actions taken to reduce the exposure. The employer may also wish to take additional measurements, e.g., area monitoring or grab sampling, to identify the sources of the excessive exposure so that rational decisions regarding methods for lowering exposure can be made.

The employer may discontinue periodic monitoring if exposure levels over two distinctly separate consecutive sampling periods show that employee exposures are below the action level

and STEL. Because of the potential for seasonable variations, an employer, once exposure has been shown to be over the action level, must conduct at least two monitoring tests to verify that the sources of emission are truly eliminated rather than simply being lowered temporarily because of seasonal variation. A similar requirement for the STEL gives OSHA some degree of confidence that the employer has adequately identified the true peak in employee exposures. OSHA has included language in the final standard to assure that consecutive sampling leading to termination of monitoring is at least seven days apart. In many industry sectors, this monitoring should be much more widely separated: the employer would not be able to assure that his or her action is appropriate unless both seasonal extremes have been examined.

Once monitoring is terminated, the employer need not resume monitoring unless there is reason to believe that employee exposures have increased to a point where they may exceed the action level or STEL.

Availability of Monitoring Methods

The final rule for formaldehyde does not specify a particular method to monitor employee exposures. Instead, the final rule is performance-oriented and requires only that employers use methods that are accurate to within plus or minus 25 percent of formaldehyde concentrations at the PELs, and plus or minus 35 percent for airborne concentrations at the action level. This performance-oriented provision remains unchanged from the proposal.

Many commenters urged OSHA not to specify a particular monitoring method because of the diversity of products that contain formaldehyde and the variety of conditions present at different facilities [Exs. 77-17; 77-19; 77-20; 77-21; 80-67; 80-71; 80-261]. Moreover, new and better methods are always being developed.

The Formaldehyde Institute reported that more than 50 methods exist for performing area and personal monitoring of formaldehyde exposures. They stated:

... The choice among the wide variety of possible monitoring methods should be made on a case-by-case basis so long as performance standards such as the NIOSH criteria for accuracy and reproducibility are satisfied. . . . Each of the monitoring methods has different characteristics which affect its suitability, accuracy and cost-efficiency in different work situations. It would not be feasible to establish by regulation the "best" monitoring methods for each of the myriad exposure scenarios [Ex. 77-19A, pp. 43-44].

After reviewing the record evidence, OSHA finds that varied exposure situations occur in the industry sectors potentially affected by the final formaldehyde standard. The Agency has therefore allowed employers the flexibility to choose among the many available monitoring methods that have sufficiently low limits of detection and the required accuracy for determining 8-hour TWA and short-term employee exposures to formaldehyde. (A synopsis of some of these methods follows).

Numerous commenters provided evidence on the availability and performance of monitoring methods for evaluating employee exposure to formaldehyde [Exs. 77-3; 77-8; 77-9; 77-10; 77-11; 77-19A; 77-26; 77-37; 77-42; 80-37; 80-38; 80-56; 80-58; 80-86A; 80-89; 86-37; 95; 97; 128A; 135; 137; 175-16; 201-5; 201-15]. These commenters generally agreed that methods are available for monitoring formaldehyde exposures over 8-hour time periods. For example, the Formaldehyde Institute submitted a review by C.J. Balmat of monitoring methods for formaldehyde in which 10 different methods were identified that are capable of measuring 8-hour TWA exposures below the action level [Ex. 77-19A, Exhibit 11]. Two NIOSH methods [Ex. 77-110] measure formaldehyde concentrations as low as 0.1 ppm. Appendix B of the final rule describes a chromatographic method presently used by OSHA, which samples by use of a solid sorbent tube. Several available passive dosimeters also meet the final rule's accuracy requirements and measure 8-hour TWA exposures to formaldehyde in the range of 0.1 to 1 ppm. [Exs. 77-19A; 77-26; 77-32; 80-38; 80-56; 97; 141; 157].

Evidence in the rulemaking record also shows that several methods are available for measuring the 2 ppm (15-minute) STEL included in the standard. For example, Balmat identified 21 methods that are capable of detecting formaldehyde at concentrations of 2 ppm averaged over 15 minutes [Ex. 77-19A, Exhibit 11]. Post-hearing comments indicate that some passive dosimeters are capable of measuring 15-minute exposures to formaldehyde [Ex. 157].

Most comments relating to the issue of monitoring methods agreed that the use of passive dosimeters is a practical way of routinely monitoring employee 8-hour TWA exposures, and that silica gel sorbent or impingers are valid methods for collecting samples for analyzing short-term exposures to formaldehyde [Exs. 77-18; 77-23; 77-32; 80-38; 80-56; 80-89; 97; 141; Tr. 5/7/86, p. 170; Tr. 5/8/86, p. 136]. Some commenters, while acknowledging that passive dosimeters are preferred for collecting 8-hour TWA

exposure measurements, expressed concern that many are inadequate for use as sampling devices for short-term exposure [Ex. 141, p. 6].

Sampling and Analysis

Early methods for sampling and analysis of employee exposure to formaldehyde were developed from air pollution techniques. Many of these methods are still in use, and some continue to rely on impingers or fritted bubblers for collection of formaldehyde. These devices are subject to breakage and spills. If a full-shift TWA sample is being collected, impingers and bubblers may require frequent changes during the shift because of evaporation of the liquid collection medium. These devices are also difficult to ship [Ex. 85-47].

Solid sorbent collection methods are more convenient than impinger methods because of their ease of use and adaptability to determining both TWAs and STELs. However, formaldehyde does not collect well in conventional sorbent tubes containing activated charcoal or silica gel. To overcome this problem, investigators have developed collection tubes that contain sorbents impregnated with agents that will react with formaldehyde to form a stable derivative. Examples are coated silica, impregnated charcoal, and coated Chromosorb 102™. According to Coyne *et al.* [Ex. 85-47], these tubes are easy to use and have good sensitivity, but they can cause problems from lack of uniformity of coating on the sorbent and short shelf life.

The chromotropic acid method was one of the first analytical techniques developed for formaldehyde. Although this method still relies on impingers/bubblers, the chromotropic acid method is recommended by the Intersociety Committee of the American Public Health Association [Ex. 85-70] and NIOSH [Tr. May 8, 1986] for the detection of formaldehyde. NIOSH's chromotropic acid method 3500 is an extremely sensitive method, capable of detecting 0.1 ppm of formaldehyde with only a 15 minute collection period.

The collecting medium generally used is 1 percent sodium bisulfite which results in a collection efficiency of greater than 95 percent. An aliquot of this liquid is mixed with chromotropic acid and concentrated sulfuric acid. The absorbance of the resultant purple chromophore is measured and the corresponding amount of formaldehyde in air is calculated (see NIOSH Method P&CAM 3500, Ex. 77-11). The working range is about 0.02 to 0.4 ppm for an 80 liter sample. Samples are stable for at least two weeks when samples are

stored in Nalgene cross-linked polyethylene bottles with non-metal caps [Ex. 86-23].

NIOSH method P&CAM 235 uses an alumina sorbent tube instead of an impinger. A major drawback to this method, however, is that the samples require immediate desorption in the field to prevent loss of formaldehyde [Ex. 86-23]. The limit of quantitation is relatively high, 0.17 mg/m³ (0.21 ppm) for a TWA sample.

The chromotropic acid method is susceptible to many interferences including phenol, ethanol, alcohols, and olefins, and these interferences create a negative bias by inhibiting color formation. Hakes *et al.* [Ex. 85-53] have developed a technique for reducing phenol interference by absorption with XAD-7TM polymeric absorbent. Several passive diffusion monitors represent adaptations of the chromotropic acid method and they generally provide some method to correct for phenol interference, as well.

In the *pararosaniline method*, formaldehyde is collected in a sodium sulfite solution in an impinger and then reacted with sodium tetrachloromercurate and pararosaniline to yield a purple chromophore measured spectrophotometrically at 560 nm. The method is relatively free from interferences. A modified method replaces the toxic tetrachloromercurate salt but may be more sensitive to temperature and interferences. Measurement limits are 2 and 1.8 ug/sample respectively. With sample volumes of 28 and 60 liter collected at 1 liter/minute, limits of quantitation are 0.07 mg/m³ (0.08 ppm) and 0.03 mg/m³ (0.04 ppm), respectively [Ex. 86-23].

The pararosaniline method has been adapted by Matthews and Howell [Ex. 144-L, Att. 12] to permit collection of formaldehyde on solid sorbent. The pararosaniline method also forms the basis of the TGM Monitor 555, which is discussed below.

The MBTH (3-methyl-2-benzothiazolone hydrochloride) method [Exs. 77-19, Method 22; 80-272] employs a midjet bubbler containing 0.05 percent MBTH. Color from ferric chloride-sulfamic acid is determined spectrophotometrically at 628 nm. The lower limit of the working range is reported to be 0.05 ppm for a 15-minute (15 liter) sample.

NIOSH Method 2502, the *(benzylamino)ethanol method* is applicable where interferences occur with the NIOSH chromotropic acid method 3500. Method 2502 uses solid sorbent tubes coated with 2-(benzylamino)ethanol for collection. The resultant cyclic oxazolidine derivative is

desorbed with isooctane and analyzed by gas chromatography. Acid mists may inactivate the sorbent. The working range is 0.25 to 4 ppm for a 12-liter sample (acceptable flow rate of 0.01 to 0.05 l/min [Ex. 80-272], so that the method is useful only for full-shift samples.

NIOSH method S-327, the *Girard-T polarographic method* was developed specifically for the Standards Completion Program and was validated over the range of the OSHA standard existing at the time. Formaldehyde is collected in a midjet fritted glass bubbler filled with Girard-T reagent and the resulting hydrazone is determined directly by polarography without preliminary workup. Other volatile aldehydes are likely interferences. The reported measurement limit is 6 ug/sample. With a sampling rate of 0.1-0.2 liter/minute and a recommended sample volume of 18 liters, the limit of quantitation is 0.3 mg/m³ [Ex. 86-23] indicating that this method is most useful for full shift sampling.

The OSHA Analytical Laboratory in Salt Lake City developed Method 1290, the *polarographic method* for determination of formaldehyde [Ex. 175-28]. Samples are collected in midjet fritted glass bubblers containing an aqueous solution of 10 percent methanol. The collected formaldehyde is derivatized with hydrazine reagent to form a hydrazone. An aliquot of the hydrazone solution is analyzed by differential pulse polarography at a dropping mercury electrode [Ex. 144-M, Att. 13]. The method has been used extensively by OSHA for its compliance program and it is free from interferences. For a 15 minute collection, the lower limit of detection is reported to be 0.1 ppm.

Coyne *et al.* found the polarographic method not particularly convenient for personal monitoring of TWA concentrations but useful for monitoring 15-30 minute excursions and 6- to 8-hour area concentrations [Ex. 85-47]. The differential pulse polarography method was described in detail in the proposal (50 FR, December 10, 1985, pp. 50496-50497).

OSHA Method 52, the *XAD-2 chromatographic method* was completed in March 1985, and it is described in detail in Appendix B. The sample is collected at a flow rate of 0.1 liter/min on an XAD-2TM sorbent coated with 2-(hydroxymethyl)piperidine. The resultant derivative is desorbed with toluene and measured by gas chromatography. There are no known interferences. For a 15-minute sample, the lower limit of detection is 0.26 ppm.

The NIOSH *oxidative charcoal tube method* P&CAM 318 uses an oxidant coated sorbent to react with collected formaldehyde and partially oxidize it. Formaldehyde is extracted with aqueous hydrogen peroxide and determined by ion chromatography. Recent NIOSH evaluations of the method revealed that samples are not stable for more than 5 days and the method is no longer used by NIOSH [Ex. 58-19]. The method is simple, however, and it might be useful for companies with in-house analytical capabilities where sample storage stability is not an important factor.

Passive Diffusion Monitors: Passive diffusion samplers are potential alternatives to impinger and sorbent tube methods for the collection of formaldehyde vapor. The appeal of these devices is their convenience, simplicity of use and minimal interference with worker activities. In many instances, passive monitors have become the method of choice for assessing workplace exposures to formaldehyde [Ex. 80-39, Att. A, p.3: Tr. May 7, 1986, p. 170].

A passive diffusion sampler collects gases at a controlled rate which is regulated by diffusion through a static layer of air or permeation through a membrane. The samplers work on the principle that a concentration gradient across the static air layer or membrane produces a mass transfer of gaseous molecules. By definition, passive monitors do not use an air moving device to transport contaminants to the collection medium, but rely on natural diffusion to ensure that a representative atmosphere is sampled by the monitor.

Several companies manufacture passive diffusion badges for formaldehyde [Exs. 77-19; 80-39, Att. A; 157; 163-B1; 163-B2; 168]. The various dosimeters each have characteristics that may make one more suitable than another under specific circumstances. However, OSHA's experience with the use of passive diffusion devices for monitoring exposure to formaldehyde indicates that these devices can be sufficiently precise and accurate to meet the requirements of this standard for monitoring formaldehyde [Ex. 125].

The 3-M company provided laboratory and field validation data on its commercially available formaldehyde monitor 3720 series [Ex. 168]. The monitor has a sensitivity of 0.8 ppm-hours with a minimum face velocity of 25 ft per min in the humidity range of 20-85 percent. Shelf life is 9 months when stored at 73°F. Phenol is an interference, but correction can be made by increasing chromotropic acid concentration in the analytical

procedure, 3-M reported and overall system accuracy of 25.6 percent at 0.1 ppm, 18.6 percent at 1 ppm, and 7.4 percent at 5 ppm.

OSHA, NIOSH, and Elia [Exs. 125; 85-61; 80-39, Att. A] have also investigated the DuPont Pro-Tec™ passive monitor. This passive diffusion monitor collects formaldehyde in a 1 percent sodium bisulfite solution for measurement by the chromatographic acid method [Ex. 77-19]. DuPont has reported that this monitor has an overall system accuracy of ± 13.1 percent in the range of 1.6 to 54 ppm-hrs.

Elia found 107 percent recovery with a reproducibility of results of 4.2 percent for 6 badges exposed at 1.4 ppm for 8 hours at 85 percent relative humidity, 50 ft/min face velocity, and 22-25°C. Similar results were seen when relative humidity was changed to 25 percent indicating that the badge is unaffected by humidity. Recovery of 0.43 ppm sampled for 16 hours at a relative humidity of 50 percent and a sampling rate of 1.63 cm³/min was 107 percent of the reference method with a standard deviation of 1.63 percent and a coefficient of variation of 3.5 percent.

The DuPont badge has a much slower sampling rate than the 3-M monitor, and it has a minimum air velocity requirement of 1 to 5 ft/min versus 15 ft/min for the 3-M monitor, although information developed by Kennedy and Hull indicates that a higher air velocity may be needed to obtain accurate results.

According to Kennedy and Hull [Ex. 85-61], the DuPont badges gave good agreement with reference concentrations under the following conditions: sampling period of 1 to 12 hours with a minimum integrated sampling loading of 4 ppm-hr; at least 3 meter per min (10 ft/min) face velocity; calculation for blank badges; and correction for loss of reagent from the samples. The DuPont badge is not well suited to short term sampling because of the initial period of time during which the badges have high variability. The badges could be stored for up to 2 weeks at room temperature after sampling with no significant sample loss.

Interferences and face velocity affected performance. Kennedy and Hull, however concluded that:

The limitations of the DuPont badge do not preclude its use for industrial hygiene sampling. If the badge is not used at face velocities of less than 3 meter-min, high phenol-to-formaldehyde ratios, and sampling times of less than one hour, then results should be equivalent to more conventional active sampling methods [Ex. 85-61, p. 104].

Direct Reading Instruments: Several direct reading instruments can give a

quick determination of airborne formaldehyde levels [Exs. 77-19; 80-272; 85-47]. The MDA Lion Formaldemeter™ is a lightweight, hand-held instrument that operates on the principle of formaldehyde reaction in an electrochemical fuel cell to produce an electric current directly proportional to its concentration. Accuracy in the 0.3 to 10 ppm range is stated by the producer to be ± 15 percent [Ex. 80-272]. It is useful for screening work areas for short-term excursions but responds to any substance spontaneously oxidized in the fuel cell including alcohols, formic acid, phenol, and resorcinol [Exs. 80-272; 85-47].

The TGM 555 Toxic Gas Monitor™ is an automated analyzer weighing about 30 pounds. Acid-bleached pararosaniline is automatically added to a scrubber solution containing a sodium tetrachloromercurate solution with sodium sulfite. This monitor detects 0.003 ppm to 10 ppm of formaldehyde. There are no known interferences [Exs. 77-19; 80-272].

Other portable analyzers such as those designed to detect infrared absorption, while not specifically designed to detect formaldehyde, have sufficient sensitivity to measure formaldehyde concentrations at the PELs.

The detector tube is a direct reading device for determining the concentration of a variety of gases in the air. Because of ease of use, low cost, and immediate indication of contaminant concentration, detector tubes are widely used. Contaminated air is drawn through the tube with a manually operated bellows or piston type pump. The contaminant reacts with the chemical in the tube to produce a stain which varies in length or color intensity as a function of concentration of the contaminant. The devices have limited use because of low accuracy limited concentration range, and frequent interferences. In most instances, detector tube samples are taken for the purpose of screening to determine whether or not a particular condition warrants further study [Ex. 80-39, Att. A, p. 9].

Elia tested four detector tube systems of formaldehyde under conditions of high or low humidity. The Kitagawa, MSA, and GasTech detector tubes were tested at 3 and 3.2 ppm with relative humidities of 80 and 20 percent, respectively. The Draeger tube was tested at 5.6 ppm with a relative humidity of 80 percent and at 0.94 ppm with a relative humidity of 85 or 20 percent. Accuracy values for the detector tubes were 15-150 percent, generally failing to satisfy criteria for accuracy and precision of monitoring

[Ex. 80-39, Att. A, pp. 67-68]. This does not necessarily preclude the usefulness of these devices for screening purposes to obtain an on-the-spot estimate of formaldehyde concentrations.

Employee Notification and Observation of Monitoring

Employers are required to notify employees of their exposures to formaldehyde within 15 calendar days following receipt of the monitoring results. The employees to be notified include those who were monitored in order to characterize workplace exposures and employees whose exposure determination was calculated from the measurement made of a representative employee's exposure. If employee exposures exceed either of the PELs, the employer must implement a written plan to reduce employee exposures. The employer must also provide the affected employees with a written description of the corrective action that will be taken to reduce exposures. Written notice may be provided to employees either individually or by posing the information at a work location that is accessible to all employees.

The final rule, like the proposal, requires that employers provide employees or their representatives with an opportunity to observe exposure monitoring and requires employers to provide the observer with any necessary protective clothing or equipment. These requirements are consistent with section 8(c)(3) of the Act, which requires OSHA to include such provisions in its health standards.

These requirements were the subject of few comments [Exs. 80-25; 80-37; 80-65; 85-111D]. Jagtar Sekhon, Standards Coordinator for the Department of Industrial Relations, CAL/OSHA Program Office, suggested that OSHA require direct written notification rather than allow employers to post the results of monitoring. Other comments were generally supportive of the proposed provisions requiring employee notification and observation of monitoring [Ex. 80-65]. OSHA's experience with other health standards indicates that a performance-oriented approach to employee notification is appropriate as long as employees have access to the data that describe their exposures to toxic substances. OSHA believes that posting monitoring results and informing employees of controls that will be implemented in cases where the PEL is exceeded will adequately inform employees of their exposure to formaldehyde.

Paragraph (e)—Regulated Areas

Paragraph (e)(1) requires employers to establish regulated areas at locations in the workplace where the concentration of airborne formaldehyde exceeds either of the PELs. In addition, employers are obligated to post all entrances and accessways to regulated areas with signs warning:

DANGER**IRRITANT AND POTENTIAL CANCER HAZARD****FORMALDEHYDE****AUTHORIZED PERSONNEL ONLY**

and to permit only authorized persons who have been trained to recognize the hazards of formaldehyde to enter such areas. Paragraph (e)(3) additionally stipulates that, whenever an employer at a multi-employer worksite establishes a regulated area, that employer must inform other employers with work operations at the same worksite of the access restrictions and locations of any such areas. These regulated area provisions have two principal purposes: (1) To prevent unnecessary or inadvertent exposure to a carcinogen; and (2) to limit the number of individuals exposed to formaldehyde's irritant effects.

The final rule clearly states that employers must establish regulated areas wherever workplace conditions exceed either PEL. Thus, entry into all areas where the 1 ppm level is exceeded over the full workshift and all areas where the 2 ppm level is exceeded in any 15-minute period within the working day must be regulated. This change has been made to conform this requirement to the inclusion of the STEL in the standard.

Even though the concept of a "regulated area" relates to the need to limit the number of persons exposed to a carcinogen, formaldehyde presents both an irritation hazard and a cancer hazard when exposure is over the TWA or the STEL. Consequently, OSHA has determined that the warning sign to be posted at the entrances and accessways to regulated areas must include information on both hazards. The sign now indicates both hazards by stating "IRRITANT and POTENTIAL CANCER HAZARD".

Many rulemaking participants endorsed the establishment of regulated areas and reported that such areas are currently being used in formaldehyde-using facilities. [Exs. 80-37; 80-65; 80-77; 85-111D; Tr. 5/7/86, p. 17]. Michael Larsen, of the Occupational Medical Center, testified:

I am in favor of the establishment of regulated areas. The regulated area has [been] found to be a useful management tool in regulating employee access to areas where potentially harmful exposures may exist. It is normally used where potentially carcinogenic materials may be in use. In the case of formaldehyde, it may also be useful to limit employee exposures to areas where formaldehyde may exist because of the risk of allergic sensitization. The delineation of a regulated area also notifies employees of required safety equipment which is necessary within the area [Ex. Tr. 5/7/86, p. 17].

Proposed paragraph (e)(1) required the establishment of regulated areas "where exposures to formaldehyde may exceed the PEL." The final rule substitutes the phrase "concentrations of airborne formaldehyde" for the term "formaldehyde" to clarify that the trigger for the establishment of a regulated area is airborne concentration. Thus, the area must be posted even if workers are not routinely in an area that has a high airborne concentration of formaldehyde, as long as they enter the area occasionally. The inclusion of this phrase in the final rule is intended to clarify the Agency's intent.

Other rulemaking participants commented on the same proposed paragraph. Ted Bauer, speaking for the Medford Corporation, a producer of plywood and fiberboard, stated that establishing a regulated area on the basis of an exposure that may exceed the PEL is inappropriate and that regulated areas should be required only when exposure actually exceeds the PEL [Ex. 80-37].

Representatives of the National Particleboard Association (NPA). William McCredie and Brock Landry questioned: (1) Whether an area exceeding a PEL must be posted even if workers do not routinely work there; and (2) whether an area with a high reading for some part of the workshift that is not above the PEL must be posted [Ex. 80-79, Attachment 1, p. 35].

Employers must post all areas where it would be possible for an employee to be exposed above either of the PELs; that is, all areas must be posted that may have airborne concentrations above 2 ppm for 15 minutes or above 1 ppm for an 8 hour period. Such areas must be posted even when no employee is routinely assigned to the area; the potential for overexposure is the determining factor. However, where the reading is high for any period of the workshift but does not exceed either of the PELs, employers are not required to post the area. OSHA's intent is to alert persons who may be in the workplace about the location of areas where they should not enter unless they are authorized to do so. Employers must

establish such an area wherever a reasonable person might not otherwise recognize access restrictions to prevent overexposure. Accordingly, employers are not required to post vessels or tanks that a reasonable person would not enter without authorization.

In rare cases, the 8-hour TWA may be exceeded and the 15-minute STEL may be achieved. In such circumstances, employers may need to clarify access restrictions on the sign demarcating the regulated area. This flexibility should allow employers to address the concern of the NPA representatives about demarcating areas where exposures are only high for a part of the workshift.

Other rulemaking participants took issue with the information proposed for signs demarcating regulated areas. These commenters [Exs. 80-79, 80-85] objected particularly to the proposed "POTENTIAL CANCER HAZARD" warning. For example, the Celanese Chemical Company, a producer of chemicals, fibers, and specialty materials, stated that such signs create unwarranted and invalid concerns about health effects associated with formaldehyde exposure * * * [Ex. 80-85, Attach. 1, p. 4].

OSHA does not agree that the posting of cancer warning signs creates "unwarranted and invalid concerns" about the hazardous effects of formaldehyde exposure. The Agency believes strongly in the importance of informing employees about workplace hazards and has traditionally found warning signs to be effective means for providing such information.

In the final rule, OSHA has added the requirements that anyone entering a regulated area must "have been trained to recognize the hazards of formaldehyde." OSHA believes that this approach places the appropriate emphasis on the principal aspects of the regulated area requirements: training, protection, and authorization.

Paragraph (e)(2) limits access to regulated areas to authorized persons trained to recognize the hazards of formaldehyde. This requirement is consistent with this standard's emphasis on the importance of hazard recognition for employees handling formaldehyde and with the training requirements in paragraph (n). The requirement that access to regulated areas be limited to authorized persons is a standard provision in OSHA health standards. This requirement is intended to work together with the other requirements in this paragraph to limit the number of employees exposed above the 8-hour TWA or the 15-minute STEL.

Paragraph (e)(3) obligates employers at a multi-employer worksite who have established a regulated area to tell other employers working at the same worksite about the access restrictions and location of such areas. Although OSHA received no comments specifically addressing this proposed requirement, this provision is particularly important on construction industry worksites, which typically involve employees of many employers working in the same or adjacent areas. This provision is included in the final rule to emphasize the responsibility that an employer has to protect his or her employees and any other person required to work at the same site from any unnecessary exposure to formaldehyde at levels above either of the PELs. Communicating with other employers at a given worksite and posting restricted areas with warnings will help to ensure that no employee at the worksite is inadvertently exposed to a formaldehyde concentration that exceeds either of the PELs and will help secondary employers fulfill their obligations to provide a safe workplace for their employees.

Paragraph (f)—Methods of Compliance

The final standard requires employers to institute engineering and work practice controls as the primary means of reducing and maintaining employee exposures to formaldehyde to levels at or below the permissible exposure limits. Moreover, whenever the employer establishes that feasible engineering and work practice controls are inadequate to lower exposures sufficiently to or below either of the PELs, controls must be applied to reduce employee exposures to the extent possible, and employers must provide supplemental protection through the use of respirators, selected in accordance with paragraph (g). The method of compliance requirements in the final rule are similar to those in the proposal except that the STEL has been incorporated to accurately reflect the PEL requirements in the final rule.

This primary reliance on engineering controls and work practices is consistent with good industrial hygiene practice and with the Agency's traditional adherence to a hierarchy of controls. This hierarchy specifies that engineering controls and work practices are to be used in preference to respirators. Respirators may be used by employers only in emergencies or where engineering or work practice controls are not feasible, not adequate, or have not yet been installed. Engineering controls involve the installation of equipment, such as forced ventilation, or

the modification of a process, such as enclosing it. Work practice controls reduce workplace exposures by altering the manner in which a task is performed. An example of a work practice control would be training an employee taking quality control samples on a railcar filled with formaldehyde to stand upwind rather than downwind of the tank car's hatch when taking the sample.

Respirators have traditionally been accorded the last position in the hierarchy of controls because there are of problems associated with their use. To be used effectively, respirators must be individually selected and fitted, conscientiously worn, regularly maintained, and replaced as necessary. In many workplaces, these conditions are difficult, if not impossible, to satisfy. Furthermore, formaldehyde has properties which make respiratory protection programs difficult to implement. For example, eye irritation caused by formaldehyde at concentrations near the PELs makes it impossible to use half-mask respirators. This limits the choice of respirators. The respirator cartridges and canisters used to remove formaldehyde gas from the inhaled breathing zone of employees wearing negative-pressure respirators have limited capacity. When the filter medium is used up, breakthrough occurs. Since formaldehyde changes the ability to smell—both as a result of long-term exposure and adaptation—and has a low odor threshold, employees and employers may have a false sense of security that they may rely on odor to detect respirator failure or breakthrough.

Other ergonomic factors apply; often work is strenuous and the increased breathing resistance of the respirator reduces its acceptability to employees. Several safety problems are presented by respirators. Respirators limit vision. Speech is also limited. Voice transmission through a respirator can be difficult, annoying, and fatiguing. Movement of the jaw in speaking also causes leakage. Effective communication may make the difference between a safe, efficient operation, on the one hand, and confusion, especially in difficult and dangerous jobs, on the other hand. Also skin irritation can result from wearing a respirator in hot, humid conditions. Such irritation can cause considerable distress and disrupt work schedules. The extent of this problem may be great in this case because formaldehyde is a skin irritant, and when present in a particulate, can become trapped between the respirator facepiece and the skin.

Thus, according to the hierarchy of controls concept, use of installed equipment, such as local exhaust ventilation, is a superior compliance method because its effectiveness does not depend to any marked degree on human behavior, and the operation of such equipment is not as vulnerable to human error as is personal protective equipment. The Agency has also found that modified work practices (*i.e.*, changing the procedures used by employees to perform certain tasks) can aid in achieving compliance with the PELs.

In some circumstances (*e.g.*, certain maintenance and repair operations, emergencies, or during periods when equipment is being installed), OSHA recognizes that respirators may be essential to guarantee worker health and safety, and provision is made in paragraph (g) for their use as primary controls in these instances. OSHA is aware that there may be other circumstances where feasible work practices and engineering controls alone cannot reduce exposure levels to the PELs because of unique conditions or features in a particular workplace. In these situations, the burden of proof of infeasibility is appropriately placed on the employer, because the employer has the best knowledge of conditions specific to that workplace; the types of control equipment that are available and suitable for controlling emissions in the affected workplace, the extent to which work practices can be modified to reduce employee exposures, and alternative methods to achieve the same goals.

Where engineering controls are not feasible or cannot achieve compliance with the PELs, employers are required to use respiratory protection to protect their employees from overexposure.

In addition to engineering controls, work practices, and personal protective equipment, the hierarchy of controls includes another compliance strategy—administrative controls. Administrative controls utilize methods such as scheduling to reduce a particular employee's total exposure. An example of the acceptable use of scheduling is performing an operation where formaldehyde exposure occurs on the work shift with the fewest employees present.

Worker rotation, however, is an administrative control that OSHA discourages as a method of complying with the permissible exposure limits. The Agency's determination regarding formaldehyde's carcinogenic potential provides a compelling reason to refrain from the practice; although worker

rotation may reduce the exposure of the individual employee, it places more employees at risk.

There were few comments to the record that addressed worker rotation [Exs. 77-2; 77-9; 77-11; 77-23; 80-65]; most of these indicated that rotation is not generally a good compliance strategy. Dr. Millar, for example, stated that "NIOSH opposes the use of worker rotation to achieve compliance in all circumstances" [Ex. 77-11, p. 3].

The overwhelming majority of commenters indicated support for or current usage of engineering and work practice controls to reduce employee exposures to formaldehyde [Exs. 77-8; 77-9; 77-11; 77-12; 77-16; 77-17; 77-18; 77-23; 77-32; 77-36; 77-40; 80-23; 80-50; 80-56; 80-65; 80-100; 80-257; 80-272; 122; 128; 135; 170; 173; 200-8; Tr. 5/7/86, pp. 14, 174; Tr. 5/8/86, p. 15; Tr. 5/13/86, pp. 136-137; Tr. 5/14/86, pp. 9, 137-138, 229-241; Tr. 5/15/86, pp. 6-7; Tr. 5/16/86, pp. 93-94]. For example, Clifford Howlett of the Georgia Pacific Corporation and moderator of the Formaldehyde Institute's Technological and Economic Feasibility Panel, stated:

It's our feeling that engineering controls, clearly on an overall workplace-type exposure, would be the preference and that's the approach we have taken [Tr. 5/14/86, p. 9].

Another endorsement of the hierarchy of controls concept was voiced by Michael Larsen:

I am fully supportive of the methods of compliance, section (f), of the proposed standard. I feel strongly that the routine use of respiratory protective equipment as a means of lowering exposure to formaldehyde should be minimized * * * [Tr. 5/7/86, p. 14].

A few commenters preferred greater flexibility in the methods of compliance permitted in the standards [Exs. 77-35, 77-37, 80-46, 80-55, 80-81, 80-261]. James B. MacRae, Jr., representing the OMB, disputed the superiority of engineering controls:

- Engineering controls require constant maintenance and upkeep, just as respirators do, to ensure that they have not failed.

- Engineering controls frequently cost more than respirators, diverting resources away from more effective safety and health investments.

- Engineering controls can endanger a larger number of workers when they fail than respirators. A failed ventilation system, for example, can endanger workers in an entire working area, whereas a failed respirator will endanger one worker. In addition, in a well-run respirator program respirators are checked daily for effectiveness. Maintenance checks on engineering controls are less frequent and are not readily verified by the population-at-risk.

- Respirators can be used effectively to protect workers from intense, short-term

exposures, whereas engineering controls are often ineffective and costly protection against short-term excursions [Ex. 80-261, p. 89].

OSHA finds this reasoning unpersuasive, agreeing instead with the views of Melvin W. First, Sc.D., Professor of Environmental Health Engineering at the Harvard School of Public Health, whose experience in the control of workplace hazards is extensive. Dr. First stated:

* * * [the statement by OMB that] a well-run respirator program can * * * [provide] better protection more cheaply than can engineering controls * * * flies in the face of oft-repeated statements by the most experienced industrial hygienists as well as the official position of NIOSH that in-plant health and safety is the responsibility of the employer and that this responsibility is best discharged by employing engineered * * * safeguards as opposed to personal protective measures or administrative controls [Tr. 5/16/86, p. 93].

Whatever cost savings may be realized by employers from * * * what OMB refers to as 'compliance flexibility' and that emphasizes respirator usage over engineering controls, solely on the basis of alleged lesser costs, is knowingly transferring responsibility for worker safety from the employer to the employee * * *. The cost of acceptable respirator programs is especially onerous for small industries that must spread the considerable administrative costs of a fully acceptable system over a few users [Tr. 5/15/86, p. 94].

* * * [it] is an open secret that workers abhor NIOSH-approved and hence effective respirators and do not willingly wear them. When they do use them at all they characteristically wear them in the most comfortable position, which means that they give less than rated protection factors * * *. Respiratory protection is, in practice, ineffective for routine worker protection and is not, therefore an acceptable substitute for engineering controls [Ex. 128, p. 39].

Dr. First also questioned the accuracy of OMB's statement that "engineering controls can endanger a larger number of workers when they fail than respirators" * * *. According to Dr. First, the statement is based on unverified assumptions, "such as that workers are more readily aware of respirator failures than engineering control failures." Dr. First also felt that OMB's statement failed to consider that engineering controls tend to deteriorate "slowly rather than suddenly and catastrophically. Periodic checks on a 6-12 month cycle are * * * adequate for maintaining them * * *" [Ex. 128, p. 40].

There are many hidden costs involved in establishing and operating effective respiratory protection programs. For example, the use of respirators triggers medical surveillance and maintenance and repair provisions under the respiratory protection standard (29 CFR

1910.134), as well as requirements for much more exposure monitoring as would be the case if permissible exposure limits could be met by engineering and work practice controls.

OSHA's decision in the final rule to continue to accord preferred status to the use of engineering controls as a compliance method to protect employees from exposure to formaldehyde is consistent with the policy on respiratory protection set forth in 23 CFR 1910.134(a)(1), which states the Agency's position on preventing atmospheric contamination:

This shall be accomplished as far as feasible by accepted engineering control measures (for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials.)

In addition to the methods discussed above for reducing worker exposure to formaldehyde, product substitution of less toxic materials is another acceptable way of reducing formaldehyde exposures:

Employers in the wood products and textile industries, including garment manufacturing, have successfully reduced emissions from consumer products while at the same time reducing employee exposures to formaldehyde by product substitution and reformulation (50 FR 50476).

The record evidence clearly confirms that product substitution and reformulation are effective ways to control formaldehyde exposure, both in the industries mentioned above and in the foundry industry [Exs. 77-2; 77-4; 77-9; 77-10; 77-11; 77-20; 77-31; 77-34; 77-37; 80-5; 80-6; 80-23; 80-24; 80-30; 80-56; 80-65; 80-77; 80-86; 80-269; 115; 128; 146M; 163; 170; 175-3; 200-8; 201-3K; Tr. 5/13/86, pp. 136-137; Tr. 5/14/86, pp. 137, 237; Tr. 5/15/86, p. 7]. Dr. First pointed to the technology-forcing effects of regulations in general and noted that the HUD regulations (which require that emissions from plywood and particleboard be lowered) spurred the resin industry on and that consumer objections to the resins used to produce early permanent press garments caused resin manufacturers to devise less objectionable compounds [Ex. 128, p. 19]. This viewpoint was echoed by Dr. Franklin E. Mirer, Director of the UAW Health and Safety Department, who stated:

The UAW also believes that without the driving force of an OSHA standard requiring control of exposure * * * together with a requirement that all feasible engineering controls be installed, readily avoidable exposures to formaldehyde will continue [Tr. 5/14/86, p. 230].

Based on the voluminous record in this proceeding, OSHA finds that engineering and work practice controls can be used to reduce workplace exposures to or below the PELs in almost every circumstance. OSHA believes that the record amply demonstrates that such controls will enable employers to achieve compliance. The technology needed to reduce employee exposures to these levels in all of the affected sectors is conventional, consisting of traditional control methods such as general and local exhaust ventilation and the use of lower-emitting resins, enclosures, and closed-loop sampling devices. This technology is discussed in detail in the Technological Feasibility section of the Regulatory Impact Analysis.

Certain other standards, *e.g.* Benzene (29 CFR 1910.1028) have permitted the employer to choose any combination of engineering, work practice, and respirator controls when the employer can document that the toxic substance is used in the work area for 30 or fewer days in a year on the grounds that:

Engineering controls may be impractical if used only a few days per year, and * * * respirators present fewer difficulties to the wearer if used intermittently.

The benzene final standard (1901.1028(f)(1)(iii)) states:

Where the employer can document that benzene is used in a workplace less than a total of 30 days per year, the employer shall use engineering controls, work practice controls or respiratory protection or any combination of these controls to reduce employee exposure to benzene to or below the PELs, except that employers shall use engineering and work practice controls, if feasible, to reduce exposure to or below 10 ppm as an 8 hour TWA.

This exemption was not proposed for formaldehyde although OSHA requested "comments from the public on the applications where the use of respirators has been an effective method for the control of exposures to formaldehyde" [50 FR 50476]. No evidence that a 30 day exemption was either necessary or effective was presented. Even though engineering and work practice controls are not feasible in some situations, specifically in maintenance and repair activities, such as vessel cleaning, and in emergencies, OSHA considers it especially unwarranted and, indeed, even dangerous to provide a 30 day exemption from the use of engineering controls in the case of formaldehyde since this substance presents many acute hazards.

There are several other reasons OSHA has not permitted a 30 day exemption in the final rule for formaldehyde. First, the benzene

proposal contained the 30 day exemption and the final benzene standard was an outcome of the rulemaking record. The formaldehyde proposal did not include a provision for the 30-day exemption and the rulemaking did not develop information to justify such an exemption.

Second, the 30 day exemption is inappropriate for formaldehyde. OSHA has found that engineering and work practice controls are both feasible and necessary to protect workers exposed to formaldehyde. A good example of this is the unloading of resins from trucks or rail cars, which is an intermittent and infrequent operation for most resin producers. In this situation, failure to use controls can cause a potentially dangerous situation which threatens other workers and the environment; yet engineering and work practice controls already exist that greatly limit such exposures. Another example would occur in the anatomy laboratory where a 30-day exemption from the need to install engineering controls could lead to laboratory instructors receiving respiratory protection while students are left unprotected from exposures exceeding the PELs.

The need for addressing highly intermittent uses of chemicals came about in reconsidering issues of technologic and economic feasibility for the lead standard. A legitimate concern was voiced; foundries melted recycled metals that would occasionally contain lead as an unwanted byproduct. Short of analyzing each batch of scrap, the foundry employer could not assure that lead was not present. Since OSHA was able to document that this generally occurred for less than 30 days in a year and that the resulting exposure, when averaged over the other days of nonexposure, would not unduly harm the employee even if his or her respirator failed, an exception was warranted.

This is not the case for formaldehyde. The carcinogenic potential of formaldehyde increases dramatically with increasing exposure; the dose-response relationship derived from the animal data to express cancer risk increases nonlinearly, by as much as the fifth order. Since carcinogenicity of formaldehyde may be concentration related, as opposed to cumulative-dose related, respirator failure could have severe health consequences. In addition, the acute effects of exposure at levels only slightly above the 2 ppm STEL become severe; the IDLH is only 100 ppm. Therefore, acute exposure from respirator failure can have potentially drastic health consequences.

For these reasons, OSHA does not believe that an engineering and work practice control exemption for intermittent exposures is appropriate.

OSHA also considered whether different principles should apply as to methods of compliance for the STEL, such as using respirators to meet the STEL but not the TWA. In the existing formaldehyde record, commenters did not address this option. Given the requirements to use a full facepiece respirator, the relatively low IDLH for formaldehyde, and the problems mentioned above which would also apply to the use of respirators to meet the STEL, there are reasons to consider that permitting different methods of compliance in all circumstances might be unwise. In the absence of comments on alternative approaches, OSHA believes that the provisions which require the employer to give preference to engineering controls and work practices over the use of respirators will lead to a protective and cost-effective approach. This matter is expected to arise in the proceeding on methods of compliance (see the 1987 Regulatory Program of the United States Government). If evidence appropriate to formaldehyde is submitted in the methods of compliance rulemaking, OSHA will consider making appropriate changes to the formaldehyde standard.

While there are situations where the employer will have to install engineering controls and improve work practices to lower short-term exposure of employees to formaldehyde, these controls are feasible. Most notable of these are tank car loading and unloading. Other examples are histology and pathology laboratories where hoods are used, and mortuaries where local exhaust is used. Failure to use controls in these situations, and other workplaces as well, would result in dangerous air concentrations.

Paragraph (g)—Respiratory Protection

The final standard provides for the use of respirators as a method of protecting employees from formaldehyde exposure under the following conditions: (1) During the interval necessary to install or implement feasible engineering and work practice controls, (2) in work operations such as maintenance, repair, and vessel cleaning where the employer has established that engineering and work practice controls are not feasible, (3) in work situations in which engineering and work practice controls are not yet sufficient to reduce employee exposure to or below the PELs, and (4) in emergencies. Employers must select

respirators as specified in Table 1 of the standard. A powered air-purifying respirator must be provided for the use of any employee who has difficulty in wearing a negative-pressure respirator.

The final rule also requires employers to implement a respiratory protection program that accords with 29 CFR 1910.134 (b), (d), (e), and (f), and to perform either quantitative or qualitative fit tests for all employees required by the standard to wear negative-pressure respirators. Employers must also ensure that, where air-purifying chemical cartridge respirators are worn, the cartridges or canisters are replaced with the frequency specified in the final rule. In addition, employers must allow employees required to wear respirators to leave the work area to wash their faces and respirator facepieces as necessary to prevent skin irritation.

The standard requires employers to provide respirators at no cost to the employee and to ensure that employees use the respirators properly. OSHA views this allocation of costs as necessary to effectuate the purposes of the Act. This requirement makes explicit an Agency position which has long been implicit in the promulgation of health standards under section 6(b) of the Act.

Whenever respirator use is permitted to control exposures to formaldehyde, the employer must implement a comprehensive respiratory protection program. The protection program must include the elements set forth in the general respiratory protection standard, 29 CFR 1910.134, which contains basic requirements for proper selection, fit, use, cleaning, and maintenance of respirators.

Employers must select respirators from those certified as being acceptable for protection against formaldehyde by the Mine Safety and Health Administration (MSHA) and by NIOSH under the provisions of 30 CFR Part 11.

When negative-pressure respirators are used, OSHA requires respirator fit testing because proper fit is critical to the performance of negative pressure, air-purifying respirators. With this type of respirator, a negative pressure is created within the facepiece of a properly fitted respirator when the wearer breathes. A poorly fitted respirator would allow workplace air to enter the facepiece through gaps and leaks in the seal between the face and the facepiece instead of passing through the sorbent material. Obtaining a proper fit for each employee may require the employer to provide two or three different sizes and types of masks so that an employee can select the most comfortable respirator having a

facepiece with the least leakage around the face seal. A mandatory fit testing protocol is included as Appendix E.

Under 29 CFR 1910.134, the employer must ensure that employees' respirators fit properly and leakage is minimized. By choosing from only those respirators specified in Table 1 of the standard, the employer minimizes the chance that the respirator will provide an inadequate fit since selection criteria are based on worst fits and not on averages. Respirator fit testing is conducted in an idealized setting, and fit factors found are generally much better than what could be expected under conditions of actual use. Consequently, if the employer conducts quantitative fit testing, the employer should encourage selection of full facepiece masks having a fit factor of at least 1,000.

Once the proper respirator has been selected, a simple fit test performed at the start of each shift by each employee wearing a negative-pressure respirator can demonstrate that a facepiece seal is being obtained. This test can be either a positive-pressure test, in which the exhalation valve is closed and the wearer exhales into the facepiece to produce a positive pressure, or a negative-pressure test, in which the inlet is closed and the wearer inhales so that the facepiece collapses slightly. Employees must receive training to perform this test properly.

OSHA's existing respirator protection regulation, 29 CFR 1910.134, requires the employer to properly train the employee to wear the respirator and to establish a respiratory protection program containing basic requirements for proper selection, use, cleaning, and maintenance of respirators. For employers to ensure that employees use respirators properly, OSHA has found that employees need to understand the respirator's limits and the hazard it is protecting against in order to appreciate why the employer imposes specific requirements to be followed when respirators are used.

Numerous comments were received regarding three aspects of the proposed respiratory protection paragraph: (1) Respirator selection, (2) respirator fit testing, and (3) the appropriate frequency for changing respiratory cartridges and canisters. In Table 1 of the final standard, OSHA requires that different types of respirators be selected for different levels of employee exposure. For 8-hour TWA exposures up to 10 ppm, a full facepiece respirator equipped with cartridges or canisters that are specifically approved for protection against formaldehyde is required. For 8-hour TWA exposures up to 100 ppm, OSHA requires the use of a

full facepiece respirator equipped with a chest- or back-mounted industrial size canister that is specifically approved for protection against formaldehyde, or a type C, air-supplied, demand-type respirator with a full facepiece, hood, or helmet. At formaldehyde exposure levels above 100 ppm or at unknown concentrations (e.g., emergency re-entry), a full facepiece self-contained breathing apparatus (SCBA) or a full facepiece air-supplied respirator with an auxiliary self-contained air supply is required. For firefighting situations, a full facepiece positive-pressure SCBA is required. For escape situations, employers may choose SCBAs operated in either demand or pressure-demand mode or a full-face mask negative-pressure respirator equipped with an industrial-size canister (back- or chest-mounted).

The respirator selection requirements of the final rule were addressed by many commenters [Exs. 77-32; 80-25; 80-78; 80-81; 80-89; 80-272; 86-3; Tr. 5/7/86, pp. 14-15, 215; Tr. 5/8/86, pp. 15-17, 76-77, 150]. Jagtar Sekhon of CAL/OSHA suggested that the respirators specified for use in formaldehyde concentrations in excess of 100 ppm be operated in a positive-pressure mode [Ex. 80-25, p. 2]. This was OSHA's intent in the proposal, and the Agency has reworded this requirement in the final rule to ensure that there is no misunderstanding as to the Agency's intent. Table 1 now clearly specifies that respirators used where concentrations are 100 ppm or greater or unknown be operated in a positive-pressure mode.

Mr. Sekhon also stated:

With regard to allowing the use of a gas mask in escape situations in order to extend escape times, no examples justifying this deviation from standard respiratory protection practice are provided in the proposal [Ex. 80-25, p. 2].

Contrary to this comment, the use of gas masks for escape in situations where there is no oxygen deficiency is accepted industrial hygiene practice (see, for example, Ex. 80-272). Such canisters provide sufficient escape time to protect employees from overexposure in escape situations. The sorbent capacity of such respirators is great enough when they are equipped with large industrial-size canisters to provide employees with effective protection in emergency escape, and OSHA is permitting employers to provide either SCBAs or full-face mask industrial canister respirators for emergency escape.

The final standard requires that employees be provided with powered air-purifying respirators if they

experience difficulty in using negative-pressure respirators. By using the term "difficulty," OSHA means a problem that an employee may experience with respect to the wearing of a negative-pressure respirator; for example, such difficulty might consist of discomfort in terms of obtaining sufficient air through the negative-pressure respirator or the inability to achieve an adequate fit with a respirator of this type.

Charles E. Fryman of Standard Oil disagreed with this proposed requirement, stating:

The selection of the appropriate and effective respirator for a particular job should be left to the employer. The requirement to provide this option can cause problems with existing facial hair exclusion policies and can reduce the effectiveness of the respirator program [Ex. 80-89, Attach., p. 3].

OSHA's rationale for including this provision in the final rule is to ensure that every employee required to wear a respirator for protection against formaldehyde exposure be provided with a respirator that is adequate for this purpose. In those cases where employees experience breathing difficulty or cannot obtain an appropriate fit with a negative-pressure respirator for whatever reason (facial contours, the presence of scars, facial hair, etc.), it is essential that such employees be provided with adequate protection to limit their exposure. For some employees, adequate protection can be obtained only through the use of a powered air-purifying respirator. This provision has been included in a variety of OSHA health standards (29 CFR 1910.1025, 1910.1043), and the Agency is not aware of any compliance difficulties associated with the requirement.

In the final rule, OSHA is not permitting the use of half-mask respirators at exposures above the PELs unless the employer can show that the use of goggles provides effective protection. This change is based on three factors: the need to protect the eyes as a target site affected by formaldehyde exposure; testimony that gas-type goggles, as proposed, are not presently an acceptable alternative to full-facepiece respirators [Tr. 5/7/86, pp. 174-175], and evidence that the use of full-facepiece respirators, but not half-mask respirators, is generally accepted industrial hygiene practice in the case of formaldehyde [Exs. 69-33C; 69-33D; 73-177; 73-181; 139A]. Indeed, several published MSDSs recommended the use of a full facepiece respirator at 1 ppm as a TWA or 2 ppm as a STEL long before these were legal limits. In addition, the draft *Occupational Exposure and Work Practice Guidelines for Formaldehyde*

[Ex. 80-272, p. 16] provided to OSHA by Howard L. Kusnetz, President of the American Industrial Hygiene Association (AIHA) and the NIOSH Criteria Document on formaldehyde [Ex. 42-85, p. 9], both recommend the use of a full facepiece respirator for exposures over 1 ppm to protect employees from inhalation of formaldehyde and from eye irritation.

Since formaldehyde is a potential human carcinogen, OSHA would require the use of respirators to protect employees who would otherwise be exposed at concentrations exceeding either the TWA or the STEL. In the case of formaldehyde, there is additional information that many employees would experience eye irritation at exposures exceeding 1 ppm. Once exposures exceed 2 to 3 ppm, even for short periods of time, this irritation would become intolerable. At exposures two to three times the STEL, virtually all employees would suffer intolerable eye irritation and some would develop uncontrollable tearing of the eyes, clearly a safety hazard. Thus, it is inappropriate to permit the use of half-mask respirators in such situations. In the absence of such information, respirator selection criteria would generally permit half-mask respirators for concentrations up to 10 times the PEL.

Two commenters suggested that gas-proof goggles could be used as a method of protecting employees from eye irritation while they were wearing half-mask respirators [Exs. 80-81, p. 2; 86-3, pp. 4-5]. For example, David J. Kolander of the 3-M Company requested that OSHA specify that gas-proof goggles be permitted with the use of half-mask respirators at exposures above the PELs, because full facepiece respirators are uncomfortable, heavier than half-masks, and impair visual and speaking functions [Ex. 86-3, pp. 4-5].

However, at the informal hearing, some participants pointed out several difficulties associated with the use of such goggles. Donald Hayes, M.D., of Burlington Industries stated that Burlington had purchased gas-proof goggles and tested them under actual use conditions and found them to be inadequate:

[Employees wearing gas-proof goggles] not only sweat, they tear inside these goggles. If they are gas proof, you really begin to see a fluid level in them before too long * * * [W]e decided to go with full face respirators rather than gas-proof goggles [Tr. 5/12/86, p. 173-174].

In response to questioning by Ms. Sherman of the OSHA panel on the utility of goggles, Mr. Larsen, OSHA's

expert witness, discussed a number of disadvantages:

I would * * * immediately opt for the full-faced respirator to protect against the irritant effects * * *.

As with gas-type goggles, I'm disinclined towards that because you now have an individual in two pieces of personal protective equipment, and you have to worry about the fit of two rather than a single [piece of equipment] * * *.

[Y]ou have a relative degree of confidence in the fit of a complete respirator, but there are no fitting requirements for gas-type goggles, and you will experience the same types of problems with that as you do with respirators * * *. Some people will not be able to get an adequate fit [Tr. 5/7/86, pp. 34-35].

Mr. Larsen also pointed out that the cost of supplying employees with gas-proof goggles and half-mask respirators may be higher than that for full-facepiece respirators [Tr. 5/7/86, p. 35].

OSHA's intent in proposing to permit the use of gas-proof goggles and half-mask respirators in the proposal was to provide adequate protection from acute irritation caused by formaldehyde exposure in a manner that would be comfortable and accepted by employees. Upon hearing the serious objections to the use of gas-proof goggles in combination with half-mask respirators, namely that (1) they are even less comfortable than full-facepieces, (2) that there is no acceptable method at this time to assure that the goggles fit properly, and (3) that there is presently no acceptable respirator-goggle combination that assures that the respirator will fit properly, OSHA believes that full facepiece respirators will be necessary to protect employees from exposure to formaldehyde.

OSHA acknowledges that full facepiece negative pressure respirators can be uncomfortable and that technological advances are always occurring. Consequently, at some point in time, a combination gas-proof goggle/half-mask respirator may become available. If valid data are developed that indicate the combination of a half-mask respirator and gas-proof goggles are effective means of protecting workers, the employer may use such devices under the formaldehyde standard without seeking a special exemption through the variance process.

NIOSH, in testimony to OSHA, recommended that no negative-pressure respirators be allowed to protect workers from exposure to formaldehyde [Ex. 98]. NIOSH based this position on that Agency's conclusion that formaldehyde is a "Category I occupational carcinogen" and a policy

that only a self contained breathing apparatus or an airline respirator equipped with an auxiliary self-contained breathing apparatus should be used for protection against exposure to carcinogens. However, OSHA believes that negative-pressure respirators can, under the limited conditions of use specified in Table 1 of the standard, be effective in providing adequate employee protection. Several other recent OSHA rulemaking initiatives (benzene, ethylene oxide, ethylene dibromide) have permitted the use of negative-pressure respirators for potential carcinogens, and the Agency believes that formaldehyde workers will also be afforded adequate protection if the respirator selection criteria presented in Table 1 are followed.

The final rule requires employers to provide either quantitative or qualitative fit testing at the time of initial use and at least annually thereafter for all employees required to wear negative-pressure respirators. Many commenters addressed the issue of fit testing for negative-pressure respirators. Several commenters objected to the proposed mandatory requirement for quantitative fit testing [Ex. 80-37; 80-38; 80-56; 80-58; 80-59; 80-64; 80-67; 80-71; 80-74; 80-81; 80-84; 80-261; 80-303; 85-111D; 86-1; 95; 164; Tr. 5/7/85, p. 15; Tr. 5/12/86, p. 134]. Many of these commenters objected to quantitative fit testing on the basis of the cost of the procedure compared to the cost of qualitative methods [Exs. 80-56; 80-58; 80-59; 80-67; 80-71; 80-303; 164; Tr. 5/7/86, p. 15; Tr. 5/12/86, p. 134]. Other participants noted that, although formaldehyde has the ability to impair the sense of smell, there are effective qualitative fit testing methods available [Exs. 80-38; 80-58; 80-59; 80-64; 80-71; 80-74; 80-81; 80-84; 86-3; 164]. These commenters pointed out that many qualitative methods employ test agents that use irritant smoke or saccharin rather than methods relying on odorants [Exs. 80-74; 80-81; 80-84]. For example, L.D. Taylor, Director of Safety and Industrial Hygiene for the Schering Corporation, stated:

Many companies have developed a two-fold qualitative respirator fit test procedure involving the use of isoamyl acetate followed by an irritant smoke procedure. The isoamyl acetate is used as a screening [test] to detect poorly fitting respirators. The final tests are administered via irritant smoke and do not rely on the sense of smell as an indication of leakage. Instead, a poorly fitting respirator will be detected by an involuntary employee reaction to the irritant smoke, usually in the form of coughing and/or sneezing.

Personal observation of qualitative respirator fit testing on approximately 5,000 employees has shown that a combined isoamyl acetate/irritant smoke protocol is

very effective in determining whether or not a respirator is fitting properly. In all cases where the subject was sufficiently sensitive to the test agents involved, the qualitative fit test procedure was found to identify all employees who could not get an adequate seal. Approximately 1% of this test population was unable to get a seal with the then currently available types and sizes of half-face piece respirators. These individuals were then given a quantitative fit test using the Deltec apparatus and a corn oil aerosol. In all cases, it was found that an employee was able to achieve a satisfactory protection factor of 10 or greater when using half masks that were negative fits when tested with a combination qualitative protocol. In short, the use of the combination qualitative protocol resulted in more false negative fit tests than the quantitative methodology and thus was more protective than the quantitative test [Ex. 80-84, p. 2].

Based on the evidence presented by these commenters on the effectiveness of qualitative fit test methods, OSHA has modified paragraph (g)(3)(ii) to allow either quantitative or qualitative fit test methods for negative-pressure respirators used to provide protection against exposure to formaldehyde.

Appendix E of the final rule describes the mandatory qualitative and quantitative fit test protocols that employers must use for respirator fitting. The protocol for qualitative fit testing in the final rule requires a two-tiered test using isoamyl acetate in combination with either saccharin or irritant smoke, a combination that was recommended by many rulemaking participants [Exs. 80-58; 80-59; 80-64; 80-71; 80-74; 80-81; 80-84; 86-3; 164]. The use of isoamyl acetate will screen employees for evidence of olfactory fatigue; the use of saccharin depends on the employee's sense of taste and not on odor detection; and the irritant smoke test reaction is involuntary. By using this protocol, OSHA believes that the fit tests will yield few false positive results that occur due to employee olfactory fatigue. In addition, the final rule requires that qualitative fit tests be conducted annually, rather than on the advice of a physician as originally proposed. OSHA believes that, as a consequence, employees will receive more frequent fit testing for respirator use, thus rendering the final rule's requirement at least as protective as the proposed requirement. In appropriate circumstances, physicians may specify more frequent fit testing than is required by the final rule. The final rule permits employers to conduct quantitative fit testing if they so desire.

Several commenters objected to the requirements that respirator cartridges and canisters be changed on a prescribed schedule [Exs. 80-38; 80-64;

80-74]. These participants urged OSHA to adopt a performance approach that would permit employers to decide when canisters and cartridges need changing. Stephen B. Sides, a CIH, and J. Andrew Doyle, Counsel for the National Paint and Coatings Association, stated:

OSHA also requires [in the proposal] that when negative pressure respirators are used that the canister be replaced within 48 hours of first use and cartridges be replaced at the end of the shift [Ex. 80-74; p. 8].

Similarly, David P. Lewis, Jr. of Weyerhaeuser stated that no mandatory cartridge or canister replacement schedule was necessary because formaldehyde has adequate warning properties to alert workers to the need for replacing the filter media in their respirators [Ex. 80-38; p. 11]. This view was expressed by several other industry commenters [Exs. 80-37; 80-64; 80-81]. OSHA believes that determining the appropriate frequencies for changing cartridges and canisters used to protect employees against formaldehyde exposure is too complex and important not to be specified in the final rule. Employees should receive equal and adequate protection, something not achieved by relying on odor.

Thurman B. Wensl of the International Chemical Workers Union recognized this factor when he requested that the final standard require that cartridges be replaced after every three hours of use or at the end of the shift, whichever comes first [Ex. 80-50, p. 3]. The AIHA draft *Occupational Exposure and Work Practice Guidelines for Formaldehyde* recommended a maximum service life of two to four hours for cartridges and canisters used for protection against formaldehyde exposure [EX. 80-272]. Based on the AIHA's recommendation, the final rule requires that cartridges be changed every three hours, that canisters used to provide protection from formaldehyde concentrations of less than 10 ppm be changed every four hours, and that canisters used in atmospheres of 10 to 100 ppm be changed every two hours. Because formaldehyde would migrate overnight through the trapping medium, potentially leading to inadvertent exposure, all cartridges and canisters, once used, must be changed after the workshift, regardless of the time they were actually in use.

A related issue raised by participants concerned the warning properties of formaldehyde. OSHA discussed the potential problems of relying on odor to determine when respirator breakthrough has occurred in the proposal:

Because the olfactory nerves are able to adjust to slight incremental increase in formaldehyde [Ex. 70-29], workers are unable to detect slowly developing leaks that would be expected to occur in a developing respirator failure * * *. The respirator wearer who detects the odor of formaldehyde or feels eye irritation should leave the area immediately and replace the air purifying device before re-entry. However, the ability to perceive formaldehyde dulls over time as a worker adapts to it, and the perception of odor should never be relied upon as an indicator of respirator effectiveness. [50 FR 50477]

The Agency position on this issue was supported by Michael Larsen, a certified industrial hygienist, who pointed out that only about half of all people exposed to formaldehyde can detect it at the action level and that an individual's ability to detect the odor varies considerably even on the same day [Ex. 135]. Formaldehyde exposure is also associated with other warning effects, such as eye and respiratory irritation, but OSHA finds it inappropriate to permit workers to experience formaldehyde's irritant effects before requiring that employers provide them with new cartridges or canisters. Allowing employees to be placed in such a situation would clearly be contrary to the principles of good industrial hygiene practice.

OSHA believes that the final standard's respiratory protection requirements, if implemented conscientiously by employers in a comprehensive program of respiratory protection, will provide employees who must wear respirators with adequate protection against the adverse health effects associated with formaldehyde exposure.

Paragraph (h)—Protective Equipment and Clothing

Like the proposal, the final rule contains several provisions requiring employers to provide formaldehyde-exposed employees with appropriate protective equipment and clothing. Paragraph (h) reminds all employers of their obligation to comply with the requirements of 29 CFR 1910.132 and 29 CFR 1910.133, and requires the employer to provide such clothing or equipment at no cost to the employee, and to assure that employees wear this personal protective equipment.

Paragraph (h)(1), Selection outlines how the employer must go about assuring that the intent of §§ 1910.132 and 1910.133 are being met. Protective clothing and equipment must be chosen on the basis of the form of formaldehyde (liquid, gas, solid), the conditions under which it is being used in the employer's workplace (amount, concentration), and

the hazard to be prevented (skin burns, dermatitis). Several subparagraphs of paragraph (h)(1) clarify what types of clothing or equipment OSHA considers appropriate with certain forms of formaldehyde.

Paragraph (h)(2), Maintenance of protective clothing and equipment, requires employers to assure that formaldehyde-contaminated protective equipment or clothing is ventilated and cleaned or laundered before it is reused. Employers are required to establish a storage area for formaldehyde-contaminated clothing and equipment and to label the storage areas and any containers used to store such clothing and equipment. Because most contaminated chemical protective clothing or equipment has been splashed with formaldehyde solutions, provisions in the final rule permit the employer to place these materials in a ventilated area, such as a hood, to dry before they are sent for cleaning or laundering. This treatment is ultimately less hazardous than placing wetted chemical protective clothing or equipment into sealed containers. To ensure that employees are alerted to the hazards, the area (e.g., hood) must be placarded with information that is identical to that on the label on the laundry drum.

Employers must assure: that only employees trained to recognize the hazards of formaldehyde are permitted to remove contaminated clothing and equipment for cleaning, laundering, or disposal; that no employee takes or wears contaminated equipment or clothing home; and that any person who launders, cleans, or repairs such clothing or equipment is informed of formaldehyde's hazardous effects and the procedures necessary to protect against such hazards when handling such personal protective equipment.

OSHA finds it necessary in the final rule to remind employers of their obligations under existing standards 29 CFR 1910.132 and .133 because the record showed that employees having potential skin contact with formaldehyde were experiencing skin disorders and diseases (see the Health Effects section).

The final standard provides even more specific guidance than the proposal on the types of personal protective equipment that the Agency considers appropriate. This greater specificity responds to comments from employers who interpreted the proposed protective equipment provisions as requiring more clothing and equipment than was actually the case. The Agency believes that these modifications will clarify OSHA's intent and thus provide better guidance to employers that will

aid them in complying with these requirements.

OSHA has taken into account the recommendations of NIOSH's criteria document on formaldehyde [Ex. 42-85] and the AIHA's draft *Occupational and Work Practice Guidelines for Formaldehyde* [Ex. 80-272] on personal protective equipment. The final rule closely parallels the recommendations made by those two organizations. For example, the requirements of paragraph (h) in the final rule differentiate the degree of hazard potentially associated with various forms of formaldehyde, as does the AIHA guideline document. Where concentrated formaldehyde solutions are involved, more protection is required than for dilute formaldehyde solutions that present only a minimal irritation or sensitization hazard.

Full body personal protective equipment is required to be worn when formaldehyde is present, at the IDLH concentration and by personnel who re-enter areas having high but unknown concentrations of formaldehyde, e.g., after an emergency. The AIHA recommends full body protection when the airborne concentration of formaldehyde "appreciably exceeds" the AIHA's recommended occupational exposure level of 1 ppm [Ex. 80-272]; however, OSHA has made the requirement a legal obligation in potential IDLH situations.

Paragraph (h) of the final rule, Provision and use, has been modified since the proposal. Employers are now required to provide protective equipment and clothing to employees exposed to formaldehyde only under the specific conditions of use given in paragraph (h)(1). In paragraph (h)(1) of the proposal, examples of different types of protective equipment were provided; in the final standard, paragraphs (h)(1)(i), (ii), (iii), and (iv) permit the employers latitude in determining the needs of individual employees when materials may be irritating or sensitizing. Use of chemical protective equipment impervious to formaldehyde becomes mandatory when employees are using solutions of formaldehyde sufficiently concentrated to crack their skin, causing breaks in the protective outer layers. For example, paragraph (h)(1)(i) of the final rule reads, "All contact of the eyes and skins with liquids containing 1 percent or more formaldehyde shall be prevented by the use of chemical protective clothing made of a material impervious to formaldehyde and the use of other personal protective equipment, such as goggles and face shields, as appropriate to the operation."

It is also possible that, once the outer layers of the skin are eroded, systemic absorption of formaldehyde might become a relevant factor. Consequently, OSHA believes that employers should not be given the latitude to determine what is appropriate protection in light of a clear and immediate danger posed by solutions containing 1 percent or more formaldehyde.

Other groups of workers show dermatitis from handling formaldehyde-bearing materials. In some cases, the dermal response might not be to formaldehyde; in other cases it is; in yet other cases the causative agent has not been demonstrated or the employee may react to several related chemicals, one of which is formaldehyde. What is clear, however, for instance in the garment industry, is that employees who handle products containing the highest amount of free formaldehyde are clearly at the greatest risk. The employer, through experience, is in the best position to identify products that are likely to cause dermatitis in employees. For example, apparel manufacturers can request that suppliers of cloth provide estimates of free formaldehyde content in their fabrics. Armed with this evidence or evidence that some employees are complaining of skin problems, the employer can act promptly, but only as needed, to provide his or her workers with necessary protective clothing or equipment. Overall, OSHA believes that it is highly unlikely that more than 5 percent of all workers who handle formaldehyde-releasing solids or other formaldehyde-bearing materials containing less than 1 percent formaldehyde will need to wear personal protective equipment. For example, Bureau of Labor Statistics (BLS) data [Ex. 127] indicate an incidence rate well under 1 percent for skin diseases and disorders in the garment industry.

Other provisions in paragraph (h)(1) indicate that the type of protection that is appropriate depends on the physical form of formaldehyde involved and the area of the body exposed, *i.e.*, different protection is needed to handle a 37 percent solution of formaldehyde than is appropriate for a formaldehyde-bearing resin. OSHA believes that this addresses the concerns of commenters who noted that certain operations or articles containing formaldehyde do not require employees to use protective clothing. Typical of these comments was the statement of John LeFors, General Manager of Willamette Industries, Inc., a manufacturer of wood products. Mr. LeFors stated that, as the proposal was written, the requirement for protective

clothing might have been interpreted as meaning that even employees handling certain solids containing formaldehyde, such as paper products, would have to wear protective clothing [Ex. 80-67].

Employers whose workers handled liquids containing more than 1 percent formaldehyde must provide chemical protective clothing that is sufficiently impermeable to permit the employee to complete the assigned task without the occurrence of breakthrough. Because breakthrough time depends on formaldehyde concentration and varies by manufacturer [Ex. 95; Tr. 5/8/86, p. 151], it is not possible for OSHA to specify materials that will apply in all uses. Employers will need to consult information sources, such as the ACGIH's draft *Guidelines for the Selection of Chemical Protective Clothing* (1985), for breakthrough information. OSHA is not requiring employers to perform permeation tests themselves, but it is essential to use up-to-date and accurate information obtaining from suppliers, the trade literature, NIOSH's Division of Safety Research, or other sources for guidance in the selection of chemical protective clothing in order to assure that employees are properly protected.

Paragraph (h)(2), Removal and storage, and (h)(3), cleaning and replacement, have been combined in the final standard under a single heading. Maintenance of protective equipment and clothing. This designation, which is used in the AIHA draft guidelines, appears to describe the intent of the standard more accurately than the proposed paragraph headings.

Only minor modifications have been made to the proposed provisions. The requirement for labels on containers of clothing has been modified to place emphasis on the actions that persons handling the containers must take. Since formaldehyde-bearing products may produce a host of toxic effects, OSHA has not mandated inclusion of any of them on the label. However, this change is predicated on the basis that the only persons handling formaldehyde-contaminated personal protective equipment or clothing will be trained to recognize the hazards they face. This type of label is not appropriate to alert untrained persons of formaldehyde's effect, and it is not a substitute for hazard communication requirements.

Paragraph (h)(2)(iii) is almost unchanged from the proposal; it requires that employers ensure that only persons trained to recognize the hazards of formaldehyde remove formaldehyde-contaminated material from the storage area for cleaning, laundering, or

disposal. The phrase "trained to recognize the hazards of formaldehyde" has been added to the final rule to clarify what "trained" means and to reflect the Agency's emphasis on training in hazard recognition, which is particularly important when the substance being regulated can be a hazard in all of its physical forms and is used in a multiplicity of operations and applications. Since the final rule allows only trained persons to handle formaldehyde-contaminated clothing and equipment, they will be aware of the nature of these hazards. OSHA found that the language of the proposed requirement failed to address formaldehyde's hazardous potential adequately.

The remaining paragraphs in the protective clothing and equipment section of the standard, paragraphs (h)(2) (iv), (v), and (vi), are almost unchanged from the proposal. OSHA received no comments specifically addressing these proposed provisions. However, many commenters expressed concern about these provisions in general or about specific aspects of these requirements. These issues are discussed below.

Many submissions to the record attested to formaldehyde's ability to cause respiratory, eye, and dermal irritation and allergic contact dermatitis and sensitization. According to Dr. Edward Emmett:

* * * in the U.S., formaldehyde is presently one of the most common causes of allergic sensitization of the skin. Formaldehyde sensitization is a serious condition, particularly because of the many sources of formaldehyde exposure [Tr. 5/6/86, p. 79].

In recognition of the strongly irritating and sensitizing properties of formaldehyde and the severity of the effects seen when skin comes into contact with concentrated solutions, the final standard's protective equipment and clothing requirements are comprehensive and address all aspects of the use of protective clothing, from selection to cleaning to storage and disposal. Many commenters, either in written submittals or testimony, supported such requirements for protective equipment and clothing [Exs. 77-8; 77-12; 77-18; 77-23; 77-31; 77-35; 77-40; 80-37; 80-65; 80-257; 80-272; 86-23; 97; 113; Tr. 5/6/86, pp. 51-79; Tr. 5/7/86, pp. 3-21; Tr. 5/15/86, pp. 205-229]. For example, Dr. Mirer of the UAW strongly supported a requirement that would provide "respirators and other personal protective clothing and equipment upon request to any employees exposed to

formaldehyde * * * [Ex. 77-12, p. 2]. The United Furniture Workers of America stated:

We support OSHA's provisions for protective equipment and clothing, as many of our members complain of skin and eye irritation when handling formaldehyde treated products [Ex. 80-257, p. 6].

Eunice Cole, R.N., President of the American Nurses' Association, which represents more than 185,000 workers, urged OSHA to adopt a standard requiring personal protective equipment and noted that the use of such equipment was often ignored because it was inconvenient and that not using such equipment had resulted in eyes being splashed with formaldehyde [Ex. 77-40, p. 2; Ex. 80-87, p. 1]. Splashes of concentrated solutions of formaldehyde in the eye are known to have caused blindness [Ex. 42-84].

Several industry commenters reported that they currently provide protective equipment and clothing to their employees [Exs. 77-9; 77-16; 80-269, Attachments 2, 3, 4; 85-6; 85-8; 85-10; 145]. D. Keith Ballantyne, a manager for Hess and Clark, producers of agricultural disinfectants, stated that all compounding personnel at Hess and Clark facilities must wear rubber gloves, aprons, and eye protection during dumping (weighing) operations, packaging personnel are protected from splashes by Plexiglas enclosures, and workers capping filled containers must wear gloves and eye protection [Ex. 77-8, pp. 4-5].

Daniel Shipp of the Decorative Laminate Section of the National Electrical Manufacturing Association (NEMA) stated that safety glasses, shoes, and gloves are required for employees handling industrial chemicals [Ex. 77-9, p. 7]. James Williamson, Counsel for DuPont, a manufacturer of formaldehyde, stated that DuPont supplies protective equipment to its workers; if there is a potential for aqueous formaldehyde contact with the eyes, goggles are required, and potential skin contact requires gloves to be worn [Ex. 77-16, p. 4]. Lynn Newbry, Vice President of the Medford Corporation, a forest products/particleboard company, stated that suitable protective equipment is company-supplied to any employee requiring or requesting it [Ex. 77-23, p. 2], and Dr. Wakelyn of the National Cotton Council reported that eye protection, gloves, and chemical-resistant aprons are worn by mix operators preparing permanent press finishes [Ex. 145, p. 1].

However, a few commenters stated that protective clothing and equipment requirements are unnecessary [Ex. 80-

261], inappropriate [Ex. 80-38], infeasible in certain operations [Exs. 77-32; 78-53], or redundant [Ex. 80-64]. For example, the DuPont Company argued that, since OSHA already has standards for personal protective equipment in 29 CFR 1910.132 and 1910.133, there is no need for the formaldehyde standard to contain such provisions.

Paragraph (h) requires employers to select and provide protective equipment and clothing in accordance with §§ 1910.132 and 1910.133, and thus imposes no new regulatory burden on employers who are already fully complying with and appropriately interpreting these standards. Health data indicating that dermal diseases remain frequent in formaldehyde workers, however, show that employers whose employees must handle formaldehyde need the guidance provided by the final rule's provisions to ensure that they are meeting the more general requirements. For example, § 1910.132 indicates that equipment must be provided when necessary; the final rule for formaldehyde supplements the general standard by defining when protective equipment is necessary. In addition, providing cross-references to the existing standards helps employers who may not be sufficiently familiar with OSHA's generic protective equipment standards to find them easily.

Some participants pointed out that personal protective equipment and clothing was not needed for all workers in the wood products industry [Exs. 77-2; 77-18; 80-38]. David Lewis, Jr. of Weyerhaeuser, a major producer of wood products, believed that only a "selected group of workers" rather than all potentially exposed employees in the hardwood/softwood plywood industry need protective equipment and clothing [Ex. 80-38, p. 12]. Another representative of the hardwood/softwood plywood industry, William Groah, Technical Director of HMPA, confirmed that all workers involved in hardwood plywood manufacturing do not routinely use "protective clothing or personal safety devices" [Ex. 77-18, Attachment 1, p. 6]. However, Mr. Groah added that wood products industry workers exposed to liquid resins, *e.g.*, during glue mixing, glue spreading, or cleanup operations, should have gloves, aprons, and goggles [Ex. 77-18, Attachment 1, p. 6].

OSHA agrees with these commenters that there are situations where protective clothing is not needed. The Agency believes that the language of paragraph (h)(1) of the final rule clearly delineates where protective equipment and clothing are needed and addresses these commenters' concerns that the standard only require protective

equipment and clothing where it is necessary to protect employees.

Two comments submitted in the record describe the potential difficulty associated with the wearing of gloves in hospitals and private medical laboratories during certain laboratory operations [Ex. 77-32, 78-53]. NIOSH reported that the use of gloves during the placement of cover slips on slides may be difficult, and the Michigan Hospital Association Service Corporation stated that:

Protective gloves are not generally worn because of the need to maintain manual dexterity when handling slides and tissues [Ex. 77-32, Attachment 1, pp. 1-2].

There are very few circumstances, however, where carefully selected and properly fitting gloves cannot be worn to protect the skin against contact with liquid formaldehyde. The Agency notes that heart surgeons are able to perform the most intricate manipulations and interventions despite their use of gloves and is confident that technicians, supplied with gloves of the appropriate type, can also perform the delicate task of cover slipping. Laboratory employees as a group appear to have a high incidence of adverse dermal reactions after their skin, particularly their hands, comes into contact with formaldehyde solutions (see, for example, Ex. 78-53). OSHA believes that the use of personal protective equipment in laboratories will eliminate or greatly minimize the hazards of dermal contact. As with other provisions, each employer has the option of demonstrating that the use of gloves or other protective equipment is not feasible in a particular operation. However, the Agency believes that, in most laboratory applications, there is no feasibility consideration constraining the use of such gloves. OSHA's belief is supported by the opinion of Dr. Herbert Derman, President of the College of American Pathologists, a national professional medical organization representing 10,000 pathologists, who stated:

Requirements for * * * protective clothing such as gloves when handling [formaldehyde] would provide reasonable and enforceable standards. These precautions would do much to avoid the short-term irritative effects of formaldehyde [Ex. 77-35, pp. 1-2].

Other commenters urged OSHA to be more specific regarding appropriate protective equipment and clothing [Exs. 80-272; 120; Tr. 5/8/86, p. 16]. During testimony at the formaldehyde hearings, Richard Lemen stated that "NIOSH believes chemical protective clothing should be selected based on data for specific materials when tested against

the actual penetrant * * * [Tr. 5/8/86, p. 16]. In post-hearing comments, Lori Abrams of the Public Citizen Health Research Group also recommended that the final rule either specify suitable protective clothing based on specific chemical material permeation tests under actual conditions of use or establish minimum standard criteria for assessing permeability, including testing methods and conditions of use [Ex. 120, p. 3].

The AIHA's draft document, *Occupational Exposure and Work Practice Guidelines for Formaldehyde*, recommended the use of protective clothing and gloves based on the form of formaldehyde being used and emphasized that permeation and degradation test data should be used as the basis for selection of a specific garment from a specific manufacturer [Ex. 80-272].

OSHA believes that the use of permeation and degradation data to select protective clothing represents good industrial hygiene practice and encourages employers to follow the AIHA's advice. The science of protective clothing testing is still in its infancy, however. Requiring employers to supply employees with protective equipment and clothing only if it has passed a specific permeation test would be premature and unnecessarily constraining.

The ACGIH draft *Guidelines for the Selection of Chemical Protective Clothing* (1985) list butyl rubber, neoprene, nitrile, polyvinyl chloride, and chlorinated polyethylene as materials that can provide adequate protection against a 37 percent formaldehyde solution. This list is not comprehensive and has been included merely to indicate the wide range of materials available that can provide protection against dermal contact with formaldehyde. Michael Larsen of the Occupational Medical Center reported that knowledge of the performance of a specific brand of protective clothing was often important in the evaluation of the breakthrough time for a particular article of clothing [Tr. 5/7/86, pp. 3-21]. Such information can sometimes be obtained from the manufacturer of the clothing. Mr. Larsen also recommended that the technical appendix to the final rule (Appendix A) refer to the ACGIH *Guidelines* mentioned above to aid employers in determining the appropriate material for personal protective equipment and clothing, which would allow them to maximize the protection provided for workers when such equipment is used. Accordingly, Appendix A of the final

rule refers to both the AIHA and ACGIH guidelines; OSHA believes these recommendations will help employers to comply with the final rule's protective equipment and clothing requirements.

OMB noted that the proposal's paragraph (h) provisions were more explicit than protective clothing requirements in any other OSHA health regulation. OMB objected that the hazard presented by skin contact with formaldehyde was far less than, for example, the danger of such contact with ethylene oxide, which OSHA recently regulated without such detailed protective equipment and clothing requirements [Ex. 80-251, p. 92]. However, it is highly unlikely that employees working in the facilities principally affected by OSHA's recent final rule for EtO (*i.e.*, EtO producers, ethoxylators, hospitals, medical products sterilizers, and spice manufacturers) would ever encounter EtO in liquid form. This is because EtO is a gas at room temperature; formaldehyde, on the other hand, exists commercially as a liquid and is used in this form in a large number of applications. Moreover, the wide range of uses and concentrations of formaldehyde demands greater specificity than was the case for EtO. In addition to the fact that occupational skin contact is highly likely with formaldehyde and highly unlikely with EtO, skin contact with formaldehyde is particularly hazardous because of its strongly irritating and sensitizing properties.

The Agency believes that the record in this rulemaking amply demonstrates the hazards of eye and dermal contact with formaldehyde in a broad variety of industrial applications and demonstrates that explicit information will assist employers in complying with 29 CFR 1910.132 and 1910.133. Peter Breyse stressed the importance of adequate protective clothing and equipment when working with formaldehyde and specifically endorsed the use of equipment such as chemical goggles in facilities where liquid formaldehyde could be splashed into employees' eyes [Tr. 5/7/86, pp. 174-175]. His comments also parallel the language in paragraph (h) of the final rule on chemical goggles and face shields, which is based primarily on the AIHA's draft *Guidelines* [Ex. 80-272] and the NIOSH criteria document on formaldehyde [Ex. 42-85]. The provisions in paragraph (h) are intended to aid employers by providing the information they need to protect their employees from eye and dermal contact with formaldehyde.

Paragraph (i)—Hygiene Protection

The final rule's provision for hygiene facilities contain some changes from the proposal. Paragraph (i)(1) requires employers to provide change rooms for employees who must change into protective clothing to prevent dermal contact with formaldehyde; paragraph (i)(2) mandates that conveniently located quick drench showers must be available to employees who may be splashed with formaldehyde solutions of 1 percent or greater; and paragraph (i)(3) requires employers to provide appropriate eye-wash facilities located within the immediate work area when there is any possibility that an employee's eyes may be splashed with formaldehyde solutions of 0.1 percent or greater.

The required change rooms must comply with requirements for such facilities described in 29 CFR 1910.141. Change rooms are needed to provide privacy to employees who are required to change from their work clothing into personal protective clothing to protect themselves from exposure to formaldehyde. The change facility also ensures that the workers will have an appropriate means for storing their regular clothing without contamination from formaldehyde.

Quick-drench showers and eye-wash facilities are needed to prevent potentially serious acute health effects in employees accidentally splashed with formaldehyde solutions. Quick-drench showers must have the capability to drench the employee with piped-in water applied with force, and they must be installed in the immediate vicinity of the potential exposure area so that workers may reach them quickly. Employees who do not normally wear full-body protection even though they handle concentrated formaldehyde solutions are those most likely to need quick-drench showers.

When a worker is splashed with formaldehyde, the severity of the reaction is determined by the concentration of formaldehyde and the length of time it remains in contact with the skin or eyes. A large spill will also result in a significant inhalation hazard. This hazard is reduced by removing the formaldehyde from the worker's skin or eyes and by diluting the formaldehyde concentration by applying water from the shower. Prompt removal of wet formaldehyde from the skin and clothing is thus imperative to protect workers. At OSHA's formaldehyde hearings, Peter Breyse stressed the importance of emergency showers and stated that

Drenching facilities should consist of deluge showers and * * * must be located in the immediate work area since time is critical in removing liquid formaldehyde from both the eyes and skin [Tr. 5/7/86, p. 176].

Originally, OSHA had required emergency showers for all employees exposed to formaldehyde solutions at concentrations above 0.1 percent. Review of the record now indicates to the Agency that the skin hazard is less severe than the potential injury to the eye from splashes or spills of formaldehyde solutions. Consequently, in the final rule OSHA has mandated the installation and use of emergency showers only when solutions of 1 percent or greater are in use.

Existing requirements in 29 CFR 1910.141 for lavatories should already provide employees with the means to wash formaldehyde solutions of less than 1 percent concentration off their skin and to wash their faces and respirator facepieces if they are experiencing skin irritation. These requirements thus ensure that affected employees will be able to minimize skin contact with irritating or sensitizing formaldehyde solutions.

Paragraph (i)(3) specifies that employers provide appropriate eye-wash facilities within the immediate work area for emergency use by any employee whose eyes are splashed with solutions containing 0.1 percent or more of formaldehyde. This paragraph is unchanged from the proposal.

Liquid formaldehyde can cause severe damage to the eyes; the severity of the hazard depends on the concentration of formaldehyde present. In a standard test for eye irritation, 0.005 ml of a 15 percent formalin solution (6 percent formaldehyde) applied to the eyes of rabbits caused corneal and conjunctival swelling and inflammation of the iris, reactions which are regarded as severe irritative responses [Ex. 42-87]. The National Research Council also reported a case in which the immediate flushing of the eyes of a worker splashed with 40 percent formalin saved the sight of the worker; a similarly exposed worker who did not receive treatment was blinded [Ex. 42-87]. Flushing the eyes repeatedly with a great amount of water immediately after contact is therefore an effective and essential method of preventing serious impairment. Because of the severity and potential irreversibility of the effect, the employer is required to provide eyewash fountains "if there is any possibility" of splashes in the eye, a requirement more stringent than the "may become splashed" language that triggers the emergency shower requirement.

It is important that eye-wash facilities, like quick-drench showers, be located in the immediate work area so that the flushing procedure can be performed as soon as possible after an accidental splash of liquid formaldehyde in the eyes. Such units may be portable; they should, however, permit the eye to be flushed for at least 15 minutes with appropriate pressure so as not to harm the eyes. During testimony at the hearings, Mr. Breyse was asked about the appropriate placement of emergency eye wash stations in the work area. He replied, "It should take a maximum of 15 seconds to get to the station if any severe chemical [is splashed] in the eye" [Tr. 5/7/86, p. 210].

Several other participants supported the proposed requirements for hygiene protection [Exs. 77-16; 78-54; 80-65; 97; Tr. 5/7/86, pp. 175-176]. For example, the UPIU described the requirements as "clear, enforceable and necessary" [Ex. 80-65, p. 6], and Mr. Breyse recommended that employers provide these facilities "for any employee who gets formaldehyde splashed on the face or whose skin or clothing becomes wet with formaldehyde solutions" [Ex. 97, p. 11].

James T. Williamson, attorney for E.I. du Pont de Nemours, reported that hygiene facilities are available to employees in Du Pont plants [Ex. 77-16, p. 4], and OSHA believes that change rooms, quick-drench showers, and eye-wash fountains are standard practice in the chemical producer sector. On the other hand, a few commenters representing other sectors felt that formaldehyde-exposed employees in their industry did not need such hygiene protection facilities [Exs. 80-38; 80-56]. For example, William Groah of HMPA reported that:

Formaldehyde is generally not employed in such concentrations or forms that special emergency showers are necessary or in general use in most hardwood plywood manufacturing facilities [Ex. 80-56, p. 6].

The regulatory language of the hygiene protection requirements is responsive to such concerns; that is, each provision is triggered by a specific hazard potentially posed by the use of formaldehyde. For example, paragraph (i)(1) requires employers to provide change rooms "for employees who are required to change from work clothing into protective clothing to prevent skin contact with formaldehyde." Hence employers whose workplaces are not associated with formaldehyde-related hazards of the kind requiring the use of full-body protective clothing probably will not need to provide change rooms. Similarly, paragraph (i)(2) requires

employers to provide quick-drench showers "if employees may become splashed with solutions containing 1 percent or greater formaldehyde"; clearly employers whose workplaces do not pose such hazards need not provide emergency showers. Paragraph (i)(3) also contains a conditional clause that triggers the requirement: employers must provide acceptable eyewash facilities "if there is any possibility that an employee's eyes may be splashed with solutions containing 0.1 percent or greater formaldehyde." Therefore, if a given workplace or work operation within a workplace does not have these conditions, the employer need take no action under this paragraph.

OSHA believes that the three requirements in paragraph (i) are essential components of any effective hygiene protection program for workers who may be exposed to formaldehyde through eye or dermal contact with liquid formaldehyde or formaldehyde-containing solutions, terms used interchangeably in this regulation. The record in this rulemaking provides solid support for the inclusion of these requirements in the final standard.

Paragraph (j)—Housekeeping

The final standard's housekeeping provisions are largely unchanged from those in the proposed standard. To comply with these provisions, employers are required to: (1) Institute a program for leak and spill detection; (2) perform preventive maintenance; (3) make provisions for spill containment, decontamination of the work area, and disposal of formaldehyde-contaminated waste; (4) ensure that employees involved in cleaning up formaldehyde spills are trained and suitably equipped; and (5) label sealed containers containing formaldehyde-contaminated waste with the appropriate hazard information.

The intent of each of the final rule's housekeeping provisions is to reduce to the maximum extent possible both the number of employees exposed to formaldehyde and the magnitude of such exposures. The inclusion of good housekeeping requirements in this standard is consistent with other OSHA health standards and with good industrial hygiene practice.

The proposal's housekeeping provisions received substantial support from a number of commenters [Exs. 77-9; 77-23; 78-25; 78-72; 80-65; 80-78; 85-22; 97; 110A; Tr. 5/15/86, p. 8]. For example, Clare Sullivan of the UPIU reported that the union found the proposed housekeeping requirements "clear, enforceable, and necessary" [Ex.

80-65, p. 6]. She noted that the union particularly endorsed the housekeeping paragraph's emphasis on preventive maintenance and the "proper disposal of formaldehyde-contaminated materials" [Ex. 80-65, p. 6].

Paragraph (j) of the final rule requires employers to implement a program of regular leak detection and spill clean-up; such a program must specifically include, at a minimum, regular visual inspections of operations where formaldehyde gas or liquids containing formaldehyde are in use. (Although debris from operations where solids are in use should not be permitted to accumulate, as a general principle, leaks and spills are not relevant considerations for solids). In addition, employers whose workplaces involve processes or operations that use formaldehyde gas must implement a leak detection program involving the use of "snoops," leak detectors, etc., to identify sources of formaldehyde emissions that need to be eliminated. Paragraph (j)(1) requires employers to maintain any formaldehyde-handling equipment by means of a regularly scheduled program of preventive maintenance. Such a program must include periodic leak detection surveys using methods appropriate to the physical form of formaldehyde (e.g., gas, liquid) being handled. These housekeeping requirements also have a secondary benefit, in that they may provide employers with objective data that can be used to make the determinations allowed in the monitoring sections to avoid having to monitor. For example, employers can use the results of their regular leak detection surveys to demonstrate that formaldehyde emissions in their workplaces are below the action level.

Several commenters supported these requirements for prompt spill clean-up and elimination or repair of leak sources [Exs. 77-23; 78-72; 97]. Lynn Newbry, Vice President of the Medford Corporation, a forest products-particleboard company, reported that any spills occurring in his company's facilities are quickly cleaned up [Ex. 77-23, p. 2]. On the other hand, L.D. Taylor of the Schering Corporation, a pharmaceutical manufacturing company, believes that "a routine leak detection program would generate a lot of unnecessary paperwork since the material would either be used in an area where the exposure was already known or while in storage, [where] there would be no exposure at all" [Ex. 80-84, p. 3]. Mr. Taylor asked OSHA to exempt from the periodic leak detection requirements of paragraph (j)(1) of the final rule

"research and laboratory areas where small quantities of formaldehyde are stored for reagent and laboratory use" even though he acknowledged that leakage from even one container of formalin solution could cause exposures above the action level [Ex. 80-84, p. 3]. In the final rule, OSHA has not exempted laboratories or other workplaces, for a variety of reasons. First, as noted in the preamble to the proposed rule [50 FR 50469], this standard applies specifically to health care and laboratory workers, who are often called on to handle formalin and other solutions containing a high percentage of formaldehyde. The record in this rulemaking clearly supports the inclusion of these workers, who routinely handle a broad range of hazardous chemicals, within the scope of the standard. In addition, OSHA believes that regular spill clean-up and good housekeeping are as important, if not more so, in the laboratory setting as in other general industry or construction workplaces.

Under the requirements of paragraphs (j)(2) and (j)(3), employers must make provisions to: (1) Contain any formaldehyde spill; (2) decontaminate the affected work area after such a spill; and (3) dispose of the formaldehyde-contaminated waste appropriately. Because conditions in the sectors affected by this standard including the percent of formaldehyde present in liquids being used; and the type of workplace, nature of the process, and controls in use, OSHA has written this requirement in performance language, leaving employers free to decide what methods of spill clean-up and decontamination are most appropriate to their workplaces.

The Dow Chemical Company supported this regulatory approach:

OSHA standards should be performance oriented to allow employers and employees latitude to do a job in the manner which best suits the operation and circumstances. This standard would regulate clean-up of spills of either a 37 percent formaldehyde solution or paraformaldehyde, a solid. Clean-up methods for liquids versus solids can be significantly different. To put sufficient detail on clean-up in the standard would be cumbersome and not effective. Performance oriented goals should be used such as "Spills are to be cleaned up in manner to control employee exposure" [Ex. 80-78, p. 12].

Thus, OSHA expects employers to use methods that are appropriate to their particular workplace and conditions and that are protective of their employees. For example, employers whose employees handle liquid formaldehyde are expected to comply with paragraph (j)(3) by quickly limiting the spill to the

smallest possible area to prevent spread of the hazard to adjacent areas. They are also required to correct the source of the leak, e.g., a leaking pump or seal, promptly. The importance of these procedures to employee safety and health was attested to by Mr. Breyssé, who stressed the need to include provisions in the final standard that would require the immediate clean-up of spills and the prompt elimination or repair of the source of the leak [Ex. 97].

In paragraph (j)(3), the final standard requires that workers assigned to clean up spills and repair leak sources be adequately protected by suitable protective equipment and clothing to prevent exposure during these operations. These employees must also be properly trained in the correct methods of clean-up and decontamination; this requirement serves both to protect the employees performing the clean-up and to ensure that the methods used do not exacerbate the hazard. OSHA received no comments on this provision of the proposed rule.

The final paragraph in the housekeeping section of the proposed rule, paragraph (j)(4), elicited comments from two rulemaking participants [Exs. 80-56, 80-85]. William Groah, Technical Director of the HMPA, urged OSHA not to require a warning label on formaldehyde-contaminated waste, such as trimmings and other debris because it would be "ludicrous to expect such materials * * * to be placed in sealed containers and [to] bear a warning" [Ex. 80-56, p. 51]. Stephen Block, representing the Celanese Chemical Company, Inc., commented that:

* * * *exposure to formaldehyde at workplace levels presents no significant risk of cancer.* As a result, OSHA has no legitimate basis on which to impose a cancer warning requirement * * * on * * * containers of formaldehyde-containing waste and/or debris [Ex. 80-85, p. 4] (emphasis in the original).

This provision of the final rule has been modified to clarify that not all materials must be disposed of in sealed containers; for example, wood trimmings or textile scraps are not included. Instead, OSHA intends that the highly contaminated waste or debris generated in an accidental spill should be handled in this manner. Furthermore, the label is meant to be used only to warn trained workers (i.e., those involved in spill clean-up) and only while in the plant. Once the material proceeds toward final disposal and leaves the clean-up area, EPA's hazardous waste rules come into effect, OSHA's intent is not to duplicate

regulations but to protect workers within the workplace.

OSHA does not agree with Mr. Block's assessment of the occupational risk associated with workplace exposure to formaldehyde. As discussed in the Significant Risk section, the Agency has determined that formaldehyde poses a significant potential carcinogenic as well as other health risk to exposed employees. The final rule's requirement that formaldehyde-contaminated waste and debris be placed in sealed containers that are labeled to indicate formaldehyde's hazardous nature is thus consistent with OSHA's determination of significant risk. Because the end disposal of such containers may be controlled by EPA, OSHA notes that such containers should exit the workplace in a form that meets EPA requirements.

This provision is also concordant with good industrial hygiene procedures, which are designed to ensure that workplace exposures are minimized where possible. Therefore, OSHA finds paragraph (j)(4) necessary and appropriate to protect the health of workers involved in the on-site handling of formaldehyde-contaminated waste.

A final issue raised in connection with the standard's housekeeping requirements was presented at OSHA's hearings by two members of the Formaldehyde Institute's (FI's) technical and economic feasibility panel. Clifford Howlett, Director of Government Affairs for Georgia Pacific, stated that he perceived "an area of overlapping jurisdiction" between paragraph (j)(5) and requirements of EPA's hazardous waste program [Tr. 5/13/86, p. 75; see also Tr. 5/14/86, pp. 52-54]. Although OSHA is aware that several EPA programs (e.g., those conducted under the Clean Air Act, Clean Water Act, and the Resource Conservation and Recovery Act (RCRA)), recognize the hazardous nature of formaldehyde and the potential threat posed to health and the environment by this chemical, EPA's focus is different from OSHA's. EPA is principally concerned with environmental hazards and exposures of the public to these hazards via the atmosphere, surface water, ground water, and contaminated soil. OSHA's mandate, on the other hand, is directed toward the protection of employee health and the reduction of safety and health risks in the workplace. Thus, paragraph (j)(4) is concerned with minimizing the exposures of workers cleaning up formaldehyde-contaminated waste and debris and the risk to in-plant workers in adjacent areas within the premises of the workplace. EPA's

principal emphasis under RCRA, in contrast, is on the transport to and disposal of such waste at appropriate disposal facilities.

Record comments on the proposed housekeeping provisions were almost uniformly supportive of these provisions. Accordingly, the final standard contains these provisions in essentially unaltered form. Evidence [Exs. 77-9; 77-23; 78-25; 78-72; 80-65; 80-78] submitted to the record has demonstrated that the Agency's belief that these provisions "are also consistent with current practices in a major portion of the formaldehyde industry" (50 FR 50479). As Daniel Shipp of NEMA added:

Industry recognizes that good work practices, including housekeeping, are essential elements to worker safety[,] and industry, for a long time, has been applying the most modern and up-to-date methods for achieving good housekeeping [Ex. 77-9, p. 4].

Paragraph (k)—Emergencies

Paragraph (k) presents the final rule's requirements for emergency preparedness. The final rule requires that employers who have workplaces where there is a possibility of having an emergency involving formaldehyde develop appropriate procedures to minimize injury in case of an emergency, and that appropriate portions of the procedures are implemented in case of an emergency. This is a change from the emergency plan detailed in the proposal, which was required for every workplace where there was *any* employee exposure to formaldehyde.

The proposal also required that: (1) Employees be trained in their responsibilities in the event of an emergency; (2) appropriate emergency equipment be accessible to employees in the workplace; (3) prior arrangements be made with local services for the evacuation, transportation, and treatment of employees involved in a formaldehyde-related emergency; (4) personnel be designated and appropriately equipped to handle the emergency; and (5) employees be evacuated from any emergency area, except those employees who are designated to handle the emergency.

There was some confusion as to the level of emergency planning necessary under the proposal. Clearly, it would be improbable that all of these provisions would be appropriate in all workplaces where employees were exposed to formaldehyde, because of the numerous and diverse forms and uses of formaldehyde in industry. Therefore, OSHA has adopted more performance oriented language to reflect the fact that employers need only develop

procedures compatible with their plant and uses of formaldehyde.

Another change from the proposal involves a narrowing of the scope of the proposed provision that required the development of emergency plans wherever employees were exposed to formaldehyde. The final standard is modified to require employers to provide for emergencies only where there is a possibility of an emergency. This change is based on comments submitted to the record that stated that the proposed scope of the provision was too broad; for example, several commenters objected to the requirement that all workplaces where employees are exposed to formaldehyde have an emergency plan [Exs. 80-38; 80-56; 80-68; 80-71]. David P. Lewis, Jr., of Weyerhaeuser, a wood products manufacturer, stated, "These types of [emergency programs] are appropriate [only] for a selected group of workers" instead of for "all potential exposures" [Ex. 80-38, p. 12]. Joseph G. Gerard, Vice President of the American Furniture Manufacturers Association, stated that emergency requirements are not appropriate for the furniture industry because formaldehyde is used in this sector as a resin, not a liquid [Ex. 80-68; pp. 9-10]. In a similar vein, John F. Murray, President of the Formaldehyde Institute, argued that, based on current industry practice, emergency requirements are unjustified [Ex. 80-71, p. 41].

Several commenters requested that OSHA consider using a specific formaldehyde exposure level as a trigger for the emergency provision [Exs. 80-21; 80-56; 80-58]. John N. Jordin, Vice President of Armstrong World Industries, stated that the emergency provision should be triggered whenever employers have workplaces with exposures above the action level [Ex. 80-21, p. 2]. William J. Groah of HMPA stated that facilities with ambient concentrations below the action level should only be required to develop emergency plans if spills or other events could occur that might expose workers to levels above the PEL [Ex. 80-56, pp. 10-11]. Joseph L. Wolfsberger of Monsanto suggested that an emergency situation requirement be triggered by "a specific exposure level to which the employee was exposed, e.g., 10 times the PEL" [Ex. 80-58, p. 13].

OSHA agrees with these commenters that the potential for an emergency involving formaldehyde differs substantially in the various industry sectors and that emergencies involving formaldehyde are not likely to occur in every workplace. Therefore, in the final

rule, the Agency has adopted a performance-oriented approach that will allow each employer who has a workplace with the potential for an emergency to prepare for an emergency in a manner specifically tailored for his or her facility.

This will also address one problem area ignored in the proposed, *i.e.* the workplace where quantities of formaldehyde are present but employees are not exposed. Such workplaces would clearly be covered by the emergency provisions of the final rule because there is a possibility of an emergency occurring.

OSHA finds that both the potentially severe effects of formaldehyde overexposure and the very nature of emergency situation argue against the use of a specific exposure level trigger for the emergency provisions. In an emergency, there is no time to ascertain what the precise level of exposure is; however, the anticipated level of exposure that could be associated with various types of emergencies, *e.g.*, a fire, a massive spill, etc., clearly ought to influence the nature of the emergency procedures that must be followed. For example, an emergency procedure designed to cope with a formaldehyde level 10 times the PEL, which produces lacrimation, would differ substantially from one involving levels 100 times the PEL, which can cause death. Moreover, use of a specific formaldehyde concentration to trigger the emergency provision would require that employers monitor to determine when their workplaces and reached such a level, which would impose additional monitoring burdens on employers.

In general, commenters supported the inclusion of a provision regarding formaldehyde-related emergencies [Exs. 80-53; 80-78; 80-272; 97; Tr. 5/7/86, p. 177]. OSHA believes that many work areas exist (such as those having storage tanks containing formaldehyde) where routine exposures are likely to be below the action level but where emergencies could arise (such as a tank rupture); these workplace conditions obviously call for a detailed emergency response procedure. This change is not intended to provide broad exemptions but to recognize that formaldehyde is present in many articles (for example, certain paper products) where downstream handling will not cause emergency situations. In particular, this provision clearly applies to facilitate in which formaldehyde is stored, handled, or otherwise used as a liquid or a compressed gas. Resins used to manufacture wood products or to treat textiles would also be included,

although cured resins contained in the finished product (for example, plywood, panelling, garments) would not. Workplaces such as laboratories, where formaldehyde is contained in bottles or other containers that could spill, would be required to have emergency procedures. Thus OSHA believes that requiring emergency procedures where the possibility of an emergency exists strikes an appropriate balance by eliminating unnecessary plans while maintaining worker protection.

Paragraph (1)—Medical Surveillance

In the December 1985 noticed, OSHA proposed to require that employers provide medical surveillance to all employees engaged in jobs that required the use of respirators and to employees exposed to formaldehyde in emergencies. Medical examinations were to be provided on an annual basis and were to include a medical and work history, a physical examination, pulmonary function testing, and counseling of employees having medical conditions that would be aggravated by exposure to formaldehyde. The employer was also required to make appropriate medical examinations and treatment available to employees exposed to formaldehyde in an emergency.

As a result of comments and information received during the rulemaking, the Agency has amended several of the medical surveillance provisions in the final rule. First, limited elements of the medical surveillance program now apply to all employees exposed to formaldehyde at or above the action level or above the STEL. These employees must receive annual screening through administration of a medical and occupational disease questionnaire. In addition, all persons exposed to formaldehyde are eligible to receive nonroutine screening to test for possible formaldehyde-related illness if the employer suspects that they have signs or symptoms that may be related to their exposure to formaldehyde. Any employee for whom the questionnaire is administered must be referred for additional testing if the responsible physician reviewing the questionnaire feels that such testing is warranted on the basis of the information supplied by the employee in the questionnaire. This testing must consist of: A physical examination that emphasizes skin and respiratory tract irritation and sensitization, shortness of breath, and eye irritation; any other test deemed necessary by the physician; and counseling of employees who have medical conditions that would be directly or indirectly aggravated by exposure to formaldehyde of their risks

from exposure to this chemical. In addition, persons who must wear respirators receive routine annual screening (including the questionnaire) and pulmonary function testing under the final rule. Emergency treatment would also be available in the event that prompt medical intervention for the patient's well being is necessary. All medical examinations conducted as part of this standard's requirements, including administration of the questionnaire, must be conducted under the supervision of a responsible physician at no cost to the employee.

To ensure that the responsible physician has the information needed to perform an assessment of the patient's ability to work with formaldehyde, the final rule requires the employer to provide the responsible physician with a copy of the standard and appendices A, C, D, and E; a description of the employee's job as it relates to formaldehyde exposure; the actual or representative exposure level for the employee's job; information on any personal protective equipment and respiratory protection used or to be used by the employee; information from previous medical examinations that were administered to the employee and that are under the employer's control; and, for emergencies, a description of the details surrounding the emergency.

Requiring the physician to supply the employer with a written opinion provides the employer with a medical basis to assess the employee's ability to work with formaldehyde without health impairment. Providing an employee with a copy of the physician's opinion within 15 calendar days of receipt by the employer ensures that the employee has been informed of the results of the medical examination in a timely manner. The physician should exclude findings or diagnoses which are unrelated to occupational exposure to formaldehyde in the written opinion to reassure employees participating in medical surveillance that they will not be penalized or embarrassed by the employer's obtaining information about them not directly pertinent to formaldehyde exposure. Such findings however, should be communicated to the employee directly.

The results of actual or representative employee exposure monitoring must be supplied to the physician responsible for medical surveillance. This information assists the physician in determining if an employee is likely to be at risk of harmful effects from formaldehyde exposure. A well-documented exposure history also assists the physician in determining if a disease that is observed

(e.g. dermatitis) may be related to formaldehyde exposure. It assists the physician who must recommend restrictions on the employee's occupational exposure options based on medical findings.

The standard also requires employers to obtain from the examining physician a written opinion containing the results of the medical examination (except for specific findings unrelated to the formaldehyde exposure); the physician's opinion as to whether the employee would be placed at increased risk of material health impairment as a result of exposure to formaldehyde; any recommended limitations on the employee's exposure or use of personal protective equipment; and a statement that the physician has informed the employee of any medical conditions that would be aggravated by formaldehyde exposure.

Employers are required to retain the records of the results of the medical examination and any tests performed, and they must provide a copy of the physician's written opinion to the employee within 15 days of receiving the opinion. This amended medical surveillance program protects employees and is a cost-effective approach to identifying employees whose health may be adversely affected by exposure to formaldehyde.

There was substantial support in the record in favor of medical surveillance for formaldehyde-exposed employees [Exs. 77-11; 77-31; 77-32; 77-40; 80-50; 80-87; 86-1; 86-17; 101; 173; 176; Tr. 5/5/86, pp. 101-131; Tr. 5/6/86, pp. 51-79; Tr. 5/8/86, p. 86; Tr. 5/9/86, pp. 85-94; Tr. 5/14/86, pp. 191-200; Tr. 5/15/86, pp. 4-55]. Typical of these comments was the view expressed by Dr. Mirer of the UAW, who supported medical surveillance to protect formaldehyde-exposed workers who experience adverse health effects even though airborne exposures are kept below the PEL and to identify "abnormalities in the preclinical stage" [Ex. 173, p. 53]. The Amalgamated Clothing and Textile Workers Union (ACTWU) agreed with the UAW and pointed out that all of the physicians who testified at the hearings supported and need for medical intervention for formaldehyde workers experiencing adverse health effects [Ex. 176, pp. 29-31].

Daniel Teitlebaum, M.D., described the far-reaching consequences of formaldehyde-related diseases that he had seen in his practice of medicine. According to Dr. Teitlebaum:

Whenever a generalized sensitization dermatitis has developed in my patients following local allergic phenomena, the patient has been very ill. Fever, rash, facial or

generalized edema, and systemic manifestations of illness occur. These patients require major medical intervention.

In some patients, these significant problems have resulted in lost workdays during the acute exposure periods. Some workers have had to change their jobs specifically because of formaldehyde-induced disease. They have left employment because their health problems created intolerable interference with their ability to work in the formaldehyde-exposed positions.

Formaldehyde has caused physical illness in workers. It has also resulted in job dropout and emotional and social upheaval in several workers and their families in my practice [Tr. May 5, 1986, p. 110].

It should be noted that these effects can occur at levels well below either the action level or the PELs, as evidenced by numerous NIOSH HHE reports.

According to Dr. Edward Emmett, an occupational health physician with a subspecialty in dermatology, there are three objectives to medical surveillance:

To determine whether an individual can work with the given formaldehyde exposure without adverse health effects;

To detect early on mild clinical conditions due to formaldehyde exposure so as to take appropriate preventative measures; and

To diagnose promptly occupational diseases that occur as a result of formaldehyde exposure [Tr. May 6, 1986, p. 70].

OSHA's requirement for a preplacement examination is intended to achieve the first objective. This approach for formaldehyde is consistent with the general approach of the American Occupational Medical Association (AOMA) in their recently published "Guidelines for Employees in Health Care Institutions" [Ex. 175-11, p. 518] and it also serves the useful function of establishing a general health baseline for future reference.

Consistent with Dr. Emmett's position that the purpose of the periodic examination is to detect sensitized individuals, identify the causal environmental conditions, and to take appropriate preventative measures [Tr. May 6, 1986, pp. 70-71], the AOMA stated that for health care institutions:

The health status of each employee should be reviewed periodically where there is a likelihood that workplace exposures or activities could have an adverse health effect [Ex. 175-11, p. 518].

OSHA agrees with these positions and believes that use of the medical disease questionnaire, with followup surveillance for any employee experiencing symptoms, will meet the objectives outlined by the AOMA and Dr. Emmett in the most cost-effective manner possible. Screening with the possibility for follow-up surveillance for all employees exposed to formaldehyde

above the action level and for all of those experiencing signs and symptoms regardless of their airborne exposure level is essential to identify individuals who have developed dermal reactions to formaldehyde and those who are inherently sensitive to working with formaldehyde [Ex. 42-87].

In previous rulemakings where OSHA found the effects of exposure are predominately cumulative (e.g., for Ethylene Oxide), OSHA has made medical surveillance more cost effective by limiting it to workers who have been exposed at or above the action level for at least 30 days per year. In the case of formaldehyde, which causes adverse acute effects that may be manifest within hours, such a limitation will not adequately protect workers. Thus, OSHA has made medical surveillance available to all workers but limited this surveillance to screening of employees for effects that potentially require greater medical intervention. Only if such effects exist will the employee receive additional testing through the responsible physician.

In the proposed rule, OSHA had provisions for medical examinations to be triggered by emergency exposures. These provisions were in recognition that emergency exposure to formaldehyde is potentially more severe than regular workplace exposures and can be life threatening. The route of emergency exposure and the symptoms produced may also be different than those in workers who are exposed routinely.

Except for comments on the need for emergency provisions separate from these for routine examination, OSHA received little comment on this aspect of the proposed medical surveillance program. Only one report, a draft guideline submitted by the AIHA, discussed medical management in emergencies [Ex. 80-272, pp. 19-20]. This guideline was apparently developed from information in a report, "Evaluation and Treatment of Alleged and Actual Formaldehyde Exposure—Clinical and Environmental Workup, Diagnosis, First Aid, Medical Emergency Measures, and Definitive Medical Treatment" prepared by W.C. Barnes, M.D., for the Health Research Committee of the Formaldehyde Institute. According to the AIHA Guideline [Ex. 80-272], when an employee with respiratory irritation is brought to a medical care facility, he should be checked to see that the airway is unobstructed and that he is breathing adequately. A quick history should be obtained of the exposure and type and duration of symptoms.

Examination should be made of the eyes, nose, mouth, throat, larynx, and lungs.

When excess exposure has resulted in upper respiratory and eye irritation, the AIHA Guideline recommended referral of the employee to a medical care facility. If respiratory tract irritation is minimal and coughing ceases promptly, the AIHA Guideline recommended that the employee should be observed for an hour and returned to work only if there are no further problems.

If severe exposure results in a highly irritated respiratory tract and coughing continues for more than 10 minutes, the AIHA Guideline recommended that the worker should be hospitalized for observation and treatment. These guidelines for treatment of exposure in an emergency situation appear to be reasonable guidelines for general application provided that the incidence is recorded and the employee receive follow-up surveillance if there is any possibility that sequela may develop.

Because formaldehyde solutions splashed in the eyes can cause blindness, this situation should always be considered an emergency. If the eyes are involved in a splash of formaldehyde, they must be flushed with copious amounts of water as soon as possible. Any employees exhibiting eye irritation from a splash or from excessive exposure should be referred for emergency care and receive prompt evaluation by an ophthalmologist [Ex. 80-272, p. 19].

A few commenters objected to any requirement for medical examinations for formaldehyde. Celanese, for example, indicated that they were opposed because they believed that the regulation does not address chronic effects, but acute reversible sensory irritation [Ex. 77-17, p. 22]. The Hardwood Plywood Manufacturers Association opposed medical surveillance because "its effectiveness has not been demonstrated, there are no practical tests indicating levels of formaldehyde exposure, and HMPA's members' workers are not at significant risk at the levels commonly found in the industry [Ex. 80-56].

OSHA agrees that the tests are oriented toward detection of reversible effects and not to chronic effects such as cancer. As Mr. Wolfsberger of Monsanto pointed out, screening of workers, even when they are at significant risk of developing cancer, is not a particularly effective use of medical surveillance. Dr. Silverstein of the UAW agreed, commenting that it is not necessary to have an ear, nose, and throat specialist perform routine medical examinations for formaldehyde workers. He noted,

however, that despite the difficulty in detecting nasopharyngeal cancers by inspection of the epithelial linings, the physician performing the exam "would be foolish not to [at least] look [for such evidence]" [Tr. May 14, 1986, pp. 265-268]. OSHA agrees with this position and believes that the performance orientation accorded the medical exams will give the individual responsible physician sufficient latitude to pay particular attention to referral of long term, highly exposed employees for special testing needed for enhanced cancer surveillance.

Most commenters agreed that some form of test is needed to detect early or mild clinical conditions due to formaldehyde exposure, and the record evidence shows that many employers are currently conducting medical screening for formaldehyde-exposed workers. According to John Murray of the Formaldehyde Institute, of eight high-exposure industries, 33 to 100 percent of those firms contacted had preplacement examinations, and up to 62 percent also offered periodic medical surveillance [Ex. 77-19, pp. 1-3, 1-4]. Dr. Ed Heiden elaborated on this point in his economic analysis of the formaldehyde standard conducted for the Formaldehyde Institute. The Heiden report found three affected segments where periodic medical exams were "pervasive," i.e., in foundries where interviews conducted with experts indicated that all employees receive physical exams that include pulmonary function tests; in resin production where 62 percent of the plants profiled provided annual physical exams; and in formaldehyde production where all employees were provided medical surveillance [Ex. 133, p. III-4]. The Decorative Laminate Section of NEMA also indicated that more than half of the employees in their industry receive complete physical exams every 1 to 2 years [Ex. 77-9, p. 6].

In contrast, Mr. Clifford Howlett of Georgia Pacific and Mr. William Groah testified that medical surveillance in the wood products industry is rare [Tr. May 13, 1986, Ex. 77-18]. These comments are consistent with the statement of individual companies in the wood products industry. Weyerhaeuser conducts medical monitoring for formaldehyde-exposed employees only if they will wear a respirator [Ex. 80-38]. Such employees complete disease questionnaires, pulmonary function tests, and a physical examination. Medford indicated that the company pays for medical surveillance only when employees were exposed in an emergency, had inadequate protection, and experienced symptoms beyond mild

irritation [Ex. 80-37]. Like Weyerhaeuser, Medford requires a pre-employment physical for all personnel [Ex. 77-23].

Dr. Philip Wakelyn, a textile chemist for the National Cotton Council, indicated that medical surveillance is rare in the garment industry [Ex. 80-59]. This is consistent with evidence obtained by NIOSH and reported in their HHE and Industry-wide Surveillance programs; most apparel manufacturers did not have formal medical surveillance programs [Ex. 78-16; 78-22; 78-26; 78-72]. Textile-finishing workers appear to receive medical surveillance. For example, Dr. Hayes of Burlington indicated that employees receive vision tests, audiometry, and a general examination. The need for additional tests is tailored to the specific exposure situation [Tr. 5/12/86, pp. 175-176]. Individuals with symptoms of formaldehyde-related disease are identified by medical disease questionnaires (Tr. 5/12/86, p. 159) and by occupational health nurses who are assigned to each facility (Tr. 5/12/86, p. 161).

Several large companies indicated that they perform general disease prevention testing for their employees. Du Pont provides medical surveillance to all employees over 40 years of age. This surveillance includes a medical disease questionnaire, physical examination, and pulmonary function tests [Ex. 77-16]. Occidental provides periodic examinations to all employees. This company commented that medical examination for formaldehyde exposure should emphasize the respiratory tract (pulmonary function tests) and skin [Ex. 77-37, p. 4]. Celanese conducts periodic medical surveillance of their workers, including chest X-rays, spirometry, blood analysis, and urinalysis [Ex. 77-17]. These examinations are not directed specifically to formaldehyde. Hess and Clark, an agricultural disinfectant producer, provides annual physical exams to its employees, including a medical history, examination by a physician, a 5-year computer profile of previous results, and spirometry [Ex. 77-8].

A survey of 26 formaldehyde producers, 19 resin and plastic materials manufacturers, 21 hardwood plywood manufacturers, 19 particleboard manufacturers, 2 industrial and specialty chemicals manufacturers, and 1 mineral wool insulation manufacturer indicated that preplacement medical surveillance was widespread in 1979, showing a high degree of agreement on the need for preplacement examinations in general. A survey of three funeral

service firms, however, failed to indicate that preplacement medical surveillance was the norm in that industry.

Thus, according to the record, OSHA finds that many industry sectors provide medical surveillance to their employees. In particular, the use of a standardized disease questionnaire to identify signs and symptoms that may be related to a developing disease or exposure to a toxic substance stands out.

The National Cotton Council recommended the use of a medical history questionnaire as a possible appropriate mechanism for reporting and responding to observed symptoms. The NCC indicated that these questionnaires might be part of a periodic physical examination administered to all employees. Affirmative responses on the questionnaire would be reviewed and clinically evaluated. If indicated, further testing would be ordered [Ex. 77-20, p. 7; 80-59, p. 7].

The American Textile Manufacturers Institute also suggested use of a medical history questionnaire as a method that "could get medical attention to those who need it" [Ex. 77-27, p. 1]. This position was also taken by Mr. Wolfsberger of Monsanto who stated that "employee reports of symptoms and complaints is the most effective method of medical surveillance [Ex. 80-58, pp. 12-13] and by Standard Oil which recommended that a respiratory questionnaire modeled to include inquiries about mucous membrane irritation should be used as the primary instrument of medical surveillance with more detailed evaluation to include physical exams and pulmonary function tests for those who are symptomatic [Ex. 80-89].

The Formaldehyde Institute supported use of medical questionnaires, physician referral and medical examinations for emergencies and for respirators users [Ex. 80-71, pp. 36-37]. The Institute's position was that the best method of medical surveillance is employee reporting of symptoms and referral for medical follow-up.

On the other hand, several unions expressed their preference for medical examinations. Ms. Seminario of the AFL-CIO stated that medical surveillance should include a medical and occupational history, a baseline pulmonary function test and a symptomatology questionnaire [Tr. May 14, 1986, p. 177]. Michael Silverstein, M.D., of the UAW indicated that periodic examinations by a health professional, employee training in symptom recognition, and an environment conducive to the reporting of symptoms are all useful components

of a comprehensive control strategy [Tr. May 14, 1986, pp. 265-268].

Dr. Teitlebaum commented that medical surveillance for formaldehyde must be based on careful assessment of a nonspecific grouping of signs and symptoms recognized as associated with formaldehyde exposure [Tr. May 5, 1986, p. 120].

According to Dr. Teitlebaum:

The symptoms which surround chronic respiratory irritation and chronic skin irritation are so characteristic that these symptoms can form an excellent and reliable record on which medical surveillance can be based. Moreover, the nonspecific signs which formaldehyde produced in the airways and on the skin are readily detectable by simple and inexpensive medical examination [Tr. May 5, 1986, pp. 120-121].

Dr. Teitlebaum recommended that as a minimum, medical surveillance for formaldehyde workers should include a medical and occupational history and a physical examination with special emphasis on airway function and skin disorders including atopic phenomena. The history should determine whether the patient is a smoker and has upper or lower respiratory problems as a result. The examiner should determine whether there is any other history of chronic airway disease, chronic rhinitis, bronchitis, or bronchiolitis, hay fever or asthma, hyperreactive airways, or recurrent upper respiratory problems of an infectious nature (pp. 121-122). Additional information would include any history of respiratory allergic reactions to foods, medicines, or industrial materials. If such a history is found, Dr. Teitlebaum recommended that caution should be exercised in the placement of such an individual in a formaldehyde-exposed position.

Whether or not a person with a history of allergies should work with formaldehyde is controversial. Yeung and Gryzbowski observed that patients with asthma have evidence of nonspecific bronchial hyperreactivity even during remissions and that the degree of nonspecific bronchial hyperreactivity is closely correlated with the severity of asthma. They concluded that in addition to the use of lung function measurements, there would be much to recommend inclusion of an assessment of bronchial reactivity. Such a recommendation might require a preemployment methacholine or histamine challenge test to determine bronchial reactivity [Ex. 85-88].

Dr. Harold Imbus, an occupational physician testifying for the Formaldehyde Institute [Tr. 5/12/86, p. 195], indicated that he would be reluctant to exclude a person from work with formaldehyde solely on the basis of

atopy. OSHA agrees with Dr. Imbus on this issue; in the case of formaldehyde, several studies of persons who were hyperreactive did not indicate that they responded to formaldehyde at low concentrations, *i.e.*, below the 2 ppm STEL [Exs. 73-16; 70-46]. Thus, it appears that many persons who are atopic could work comfortably in a job involving formaldehyde exposure.

Although mandating specific and expensive medical tests for all formaldehyde-exposed employees will not provide definitive information on a person's suitability for work with formaldehyde, the final rule affords the responsible physician the latitude to deal with such questions. In particular cases, a physician may need specific tests to assess a case adequately, and this flexibility is granted by the final rule's provisions that the physician do other appropriate tests.

Dr. Teitlebaum recommended that the medical surveillance program should include a physical examination giving particular attention to the airways and to the skin. If any evidence of skin irritation or sign of disturbance of the integrity of the skin is seen, Dr. Teitlebaum recommended that the physician should seriously consider the advisability of consulting with a dermatologist regarding whether the placing of such an individual in an environment where dermal contact with formaldehyde solutions would place the individual at increased risk [Tr. May 5, 1986, p. 122].

According to Dr. Teitlebaum, the remainder of the physical examination should give attention to the chest examination and to the general behavior of the patient. He also recommended that specialized tests be considered as needed. For example, the patient might be given indirect or fiberoptic laryngoscopy if he or she is complaining of hoarseness or voice changes associated with formaldehyde exposure [Tr. May 5, 1986, p. 123]. He also considered a baseline chest film useful if no X-ray has been performed within 5 years and a complete blood count as possibly useful for patients exposed to inhaled allergens. However, Dr. Teitlebaum did not consider pulmonary function tests or chest films to be necessary in the absence of significant abnormality on physical examination [Tr. May 5, 1986, p. 125].

Dr. Emmett felt that medical consultation must be made available promptly to any employee who has developed dermatitis that may be caused by or aggravated by formaldehyde. At the discretion of the evaluating physician, the employee

might be patch tested by procedures developed by the North American contact dermatitis group to determine whether sensitization to formaldehyde has developed [Tr. May 6, 1986, pp. 74-75].

Dr. Imbus testified that it would be uneconomical and possibly harmful to conduct preemployment or routine periodic patch tests on employees. Instead, a history of obvious formaldehyde-related skin problems should be sufficient, according to Dr. Imbus, to preclude a person from working with formaldehyde [Tr. May 12, 1986, pp. 192, 193].

OSHA has evaluated these suggestions and concludes that the morbidity rates expected for the average person exposed to formaldehyde at levels below 1 ppm are too low to warrant specific medical examination on a routine, periodic basis unless there is some reason to believe that the individual may be affected by formaldehyde exposure at such levels. Nevertheless, there is a subgroup of "reactors" and persons who may have skin diseases even though they are only exposed to relatively low concentrations of formaldehyde. In the event that these persons are identified through the disease questionnaire, the responsible physician may need to administer the tests indicated to determine if the signs or symptoms being experienced are truly indicative of an adverse response to formaldehyde.

Considerable testimony was received indicating that the PELs are not sufficiently low to prevent significant adverse reactions in some workers, both of a reversible and an irreversible nature. Dr. Teitlebaum stated that based on his clinical experience, "it is unlikely that * * * 1 ppm will be low enough to assure universal protection from the irritant effects of formaldehyde in all persons and in all industries. Even at a PEL of 1 ppm, some workers will suffer irritant and allergic symptoms." He also indicated that some provisions should be made to allow workers who are more sensitive to the effects of formaldehyde to have access to medical evaluation [Tr. May 5, 1986, p. 118].

Public Citizen commented that 1 ppm is too high a threshold for medical surveillance because acute irritant effects occur below this level. As support for this position, Public Citizen cited the NIOSH criteria document recommendation of a 1 ppm STEL based on irritation. Public Citizen noted that providing medical surveillance to more workers than proposed would have potential health benefits for the workers [Ex. 86-1, 101].

Ms. Margaret Seminario, of the AFL-CIO, noted that by using the PEL as the trigger for medical surveillance as proposed, many workers at risk of developing disease and suffering adverse effects of exposure would be excluded from medical monitoring [Tr. May 14, 1986, p. 175].

Dr. Emmett stated that since formaldehyde skin allergy is a reasonably frequent occurrence and atopy and other medical conditions, such as sinusitis, may be aggravated by formaldehyde exposure, preplacement or initial assignment examinations should be available to all employees who will have formaldehyde exposure of 0.5 ppm or greater [Tr. May 6, 1986, pp. 71-72].

Dr. Emmett indicated that there may even be individuals who need this examination at levels below the action level. He suggested that there should be an evaluation of jobs where there are formaldehyde exposures below the action level made by the occupational physician along with the industrial hygienist, as needed, to determine the need for preplacement examinations directed at formaldehyde exposure to the skin. According to Dr. Emmett, special consideration should be given to the likelihood of skin contact and the availability and effectiveness of engineering controls to prevent skin exposure. Where some skin exposure to formaldehyde is probably unavoidable, Dr. Emmett recommended that preplacement examinations should be performed to detect preexisting sensitivity to formaldehyde or the presence of dermatitis [Tr. May 6, 1986, pp. 72-73].

OSHA has taken these comments under advisement and agrees that medical surveillance should not be triggered solely by exposure over the PELs or even by exposures over the action level, which is inadequate to identify subgroups of persons who will develop an adverse reaction to formaldehyde. Consequently, in the final standard, the employer must establish a preplacement and periodic medical surveillance program for all workers exposed to formaldehyde at concentrations at or above the action level.

There are special circumstances involving hypersusceptible individuals or dermal exposure where medical surveillance may also be necessary even though airborne concentrations of formaldehyde are low. To assure that persons who may be experiencing adverse effects from their exposure to formaldehyde are identified, the employer must provide for

administration of a medical disease questionnaire. OSHA anticipates that these cases will be relatively rare when exposure is below the action level, and they are likely to occur on a one-time-only basis for an individual, as opposed to annual surveillance. Because observations of signs or symptoms related to formaldehyde exposure have only occurred in situations involving exposures above 0.1 ppm, OSHA would expect that such signs or symptoms would almost never occur at levels below 0.1 ppm. Only in the most exceptional circumstances would the administration of a questionnaire be called for below 0.1 ppm, such as where an employee has a history of hypersensitive reactions.

Regarding periodic examinations, Dr. Emmett recommended that they should be made available yearly to employees exposed above the action level of 0.5 ppm and to employees with sufficient skin exposure [Tr. May 6, 1986, p. 75]. Several other groups, including the UAW [Ex. 77-12] and the UPIU [Ex. 80-65] favored extending medical surveillance to all employees currently exposed to formaldehyde. Clare Sullivan of the UPIU indicated that many workers now exposed below the action level or the PEL have received much higher exposures in the past so that they are at high risk of developing chronic diseases such as cancer [Tr. May 15, 1986, p. 11].

These positions regarding the need for medical surveillance for workers who have dermal exposure or high risk of disease from past exposures have merit. Many NIOSH HHEs, for example, indicate dermal reactions in textile workers exposed below the action level. However, there must be some practical limit below which surveillance need not be accorded to every employee. By requiring the employer to make medical surveillance available to all employees when the employer suspects that they may be experiencing formaldehyde-related symptoms, OSHA believes that a proper balance between identification of high risk employees and medical examination has been struck. Thus surveillance need not be accorded to each and every worker who is potentially exposed to formaldehyde at extremely low levels. On the other hand, establishing surveillance by a three-tiered approach which clearly acknowledges the potential risks involved, is an appropriate and necessary action to prevent material impairment of health and loss of functional capacity.

OSHA's review of the record indicates that there was virtually no

support for triggering of medical surveillance at the 1 ppm PEL as proposed. Commenters were either philosophically opposed to any mandated surveillance, or of the belief that surveillance should be triggered by a medical disease questionnaire, or of the belief that surveillance should begin at some level below 1 ppm. In the final rule, OSHA has determined that medical surveillance should not be automatically excluded for the substantial number of employees who will have adverse responses to formaldehyde at levels below the TWA and the STEL. However, the degree of surveillance required is designed to precisely parallel the risk of adverse reaction experienced, on the average, by the worker.

In the proposal, OSHA specified information to be supplied to the employer, the physician, and the employee. These provisions were based on OSHA's experience with medical surveillance programs in other health standards. The provisions were noncontroversial and they are retained in the final standard.

The final standard obligates the employer to pay for the time an employee spends taking the medical examination regardless of whether or not it is taken on work time and the exam must be given at a reasonable time and place. It is necessary that exams be convenient and without loss of pay to the employee to ensure that employees do not refuse to take them.

All examinations and procedures must be performed by or under the supervision of a licensed physician and be provided without cost to the employee. Certain parts of the examination, in particular, administration of the medical disease questionnaire or the pulmonary function tests, do not necessarily require the physician's expertise and could be conducted by another person under the supervision of the physician.

Even though several physicians criticized OSHA's proposed provisions for retention of medical records [Ex. 92], OSHA has continued to make the employer responsible for their retention. Because of the employee's rights to privacy, some physicians believed that such information should not fall into the hands of persons who lack medically related training. OSHA's need to hold the employer responsible for record retention need not conflict with these professional ethics. Records may be retained by the physician under a contractual arrangement with the employer so that OSHA's requirements regarding retention and access are met without violation of medical ethics. In the final rule, OSHA has revised the

language of this provision to clarify that employers are responsible for ensuring that medical records be retained but not necessarily in the employer's possession.

In response to OSHA's Advance Notice of Proposed Rulemaking (50 FR 15179), the UAW urged OSHA to include a provision in any formaldehyde standard requiring that medical removal protection (MRP) benefits be accorded to "each employee removed from exposure to formaldehyde or otherwise limited as a result of medical findings or recommendations" [Ex. 77-12]. The UAW urged that:

In such an event, the employer should maintain the earnings, seniority and other employment rights and benefits of the employee as though the employee had not been removed from exposure to formaldehyde or otherwise limited [p. 2].

Most employee representatives [Exs. 80-50; 80-65; 80-88; 86-17; Trs. 5/13/86 (p. 206), 5/14/86 (pp. 160-162; p. 176), 5/15/86 (p. 92)] agreed with the UAW position, as did NIOSH [Tr. 5/8/86, Exs. 86-23, 98] and the Public Citizen Health Research Group [Tr. 5/9/86, Exs. 86-1, 101]. Lori Abrams, testifying for the Health Research Group, stated that:

* * * workers should be removed from areas of formaldehyde exposure to recover from acute or chronic irritant effects of exposure with retention of wages, seniority status, and other benefits * * *. Without medical removal protection, workers will be forced to choose between their jobs and their health. A decision that is entirely contrary to the intent of the OSHA Act * * * medical removal protection and wage retention are also essential components of a formaldehyde standard because they effectuate the medical surveillance provisions of the standard [Exs. 86-1, 101, p. 94].

Witnesses for ACTWU described actual situations in which employees were reluctant to jeopardize their pay and/or positions by reporting adverse health effects. Susan Pinette, a panelist for the ACTWU, testified that the textile company she works for has reversed its former policy of guaranteeing injured workers the chance to continue to work after their injury without losing pay. According to Ms. Pinette, complaining workers now are told that they cannot continue on their jobs but will instead be transferred to a "single needle" job, where

* * * it is hard to make your production and keep up your level of earnings. It is almost a punishment * * *. [Since this new policy has been in effect] even the supervisors are discouraging such reports * * * [and workers are unwilling to report symptoms] * * *. Workers need to feel that they can report their symptoms and not fear that they will be penalized as a result [Tr. 5/13/86, pp. 210-211].

The UPIU noted in its post-hearing comments that formaldehyde's sensitizing properties are unique, since sensitized persons cannot work in an atmosphere containing even trace amounts of formaldehyde without discomfort. Because this is the case, the UPIU felt that guaranteed job reassignment is necessary and that MRP is also essential if medical surveillance is to be triggered by voluntarily reported symptoms [Ex. 172].

Similarly, Dr. Silverstein of the UAW expressed his strong belief that voluntary reporting of symptoms by employees would not work unless workers are provided with medical removal protection and multiple physician review. Without these assurances, Silverstein indicated that "workers would not cooperate * * * and the standard would self-destruct" [Tr. May 14, 1986, p. 263].

The majority of employers and industry associations, however, were opposed to the inclusion of any form of MRP in the final standard [Exs. 77-19A; 80-46; 159]. Many industry commenters concurred with the position taken by the ATMI that MRP is unnecessary because there is no evidence that formaldehyde is a frequent cause of contact dermatitis or an allergic reaction in the workplace [Exs. 77-20; 77-23; 80-37; 139; 159; 164]. Further, ATMI noted that:

* * * most companies already have a complaint mechanism in place to discover individuals with problems. This includes a policy of re-assigning an employee in response to the sensitization or allergic reaction experienced by the few individuals. We believe this is the more appropriate mechanism for handling the small number of cases that arise [Ex. 159, p. 1].

The Formaldehyde Institute opposes a medical removal protection provision on the grounds that, for formaldehyde, the primary concern is acute, not chronic toxicity, and there is no objective criterion for determining when a worker should be removed (in contrast, for example, to monitoring the lead content in exposed employees' blood). Moreover, the Institute felt that, while most symptoms of formaldehyde exposure are transient and minor (*i.e.*, reversible irritation), the rare worker who has an extreme sensitization reaction will likely remain sensitized—even after his reaction subsides—and therefore may never be able to return to the same job. Thus, the Formaldehyde Institute supported the voluntary use of a complaint mechanism, implemented as part of a hazard communication program, and a policy of employee reassignment [Ex. 139, pp. 97-99].

The Agency has weighed the evidence carefully regarding medical removal protection for formaldehyde-exposed workers and has concluded that mandatory MRP is neither appropriate nor sensible in the case of formaldehyde sensitization. The record indicates that temporary removal, even of several months' duration, would be ineffective because, once sensitized, the worker is unlikely ever to tolerate exposures, however low, and thus the health of such workers must be considered permanently impaired insofar as further exposure to formaldehyde is concerned. Daniel Teitelbaum, M.D., of the Denver Clinic Medical Centers, presented a thoughtful response when cross-examined about MRP and the plight of the sensitized worker:

It [MRP] is a very practical and a very attractive idea which it seems to me doesn't quite work the way it was envisioned on the one hand. On the other hand, when we talk about any concept of medical removal in connection with formaldehyde. I get into the problem that the patients whom I see generally * * * who have persistent disease * * * probably never are going to get better and probably will never be able to go back to work in a formaldehyde exposed setting and need some other kind of fiscal protection than the medical removal protection [Tr. 5/5/86, p. 136]

OSHA believes that Dr. Teitelbaum's assessment is correct: the sensitized worker would not benefit from temporary removal from formaldehyde exposure, and thus medical removal protection clearly would not address problems of this sort. For the worker with acute irritation resulting from formaldehyde exposure, OSHA believes that a policy of reassignment for a short period, such as that described by industry representatives as usual practice, can provide the necessary and appropriate relief. The nonspecificity of signs and symptoms, which makes an accurate diagnosis of formaldehyde-induced irritation difficult and complicated, coupled with quick resolution of the effects—often within hours, combine to make specific medical removal protection provisions for controlling irritation to formaldehyde inappropriate.

OSHA also received some comments from participants who believe that multiphysician review is necessary to ensure employee cooperation with a medical surveillance program [Exs. 77-31; 80-50; 80-65; 80-88; Tr. 5/14/86, pp. 176, 199; Tr. 5/15/86, p. 57]. Dr. Michael Silverstein of the UAW, for example, urged OSHA to include in the formaldehyde standard a provision for multiple physician review such as was included in the lead standard:

Under the lead standard, an employee dissatisfied with examination by the employer's physician can select a second physician for an independent evaluation. The two doctors attempt to resolve * * * [Tr. 5/14/86, p. 199].

However, the Agency finds the multiple physicians review provision unnecessary in this standard because, unlike the situation of lead-exposed workers who must be subjected repeatedly to complex procedures to measure blood lead levels, workers exposed to formaldehyde are not required to undergo frequent and invasive testing. Further, there is no evidence that formaldehyde-exposed employees are being subjected to questionable practices, such as chelation therapy or the administration of investigative drugs, as was found in the case of lead. Thus, OSHA has no reason to believe that multiple physician review would actually improve the medical surveillance being received by workers exposed to formaldehyde.

Paragraph (m)—Hazard Communication

The proposed standard required all employers covered by the standard to comply with paragraph (e) through (j) of OSHA's generic Hazard Communication standard (29 CFR 1910.1200) and to assure that hazard warning labels were affixed to all containers of formaldehyde or formaldehyde-treated products in the workplace or leaving the workplace. In addition, the proposed standard specifically exempted from the labeling requirements the following items; furniture, garments, bedclothes, and draperies made from formaldehyde-treated fabrics. The proposal also included a provision allowing employers to use substitute labels where such labels were required by other statutes, regulations, or ordinances, provided that these other labels imparted the same information as those required by OSHA. Finally, the proposed hazard communication provisions required that all covered employers who manufacture or import formaldehyde or materials capable of releasing formaldehyde comply with the generic Hazard Communication standard's requirements pertaining to the development and updating of Material Safety Data Sheets (MSDSs). The proposal required MSDSs to be provided to employers at the time of initial shipment and at the time of the first shipment after an MSDS has been updated. Thus, the proposed standard extended the obligation of employers to provide a hazard communication program to all workplaces covered by the formaldehyde standard instead of restricting the application of these requirements only to workplaces in the

manufacturing SIC codes (20-39). By virtue of OSHA's expansion of the Hazard Communication standard (29 CFR 1910.1200) all employers will need to comply with the Hazard Communication requirements in the near future. Consequently, modifications to hazard communication in the formaldehyde standard have been made to reflect the overall change in the status of the regulations.

The hazard communication provisions of the final standard, like the proposal, apply to all workplaces covered by the standard. These provisions are consistent with OSHA's Hazard Communication standard (48 FR 53280, November 25, 1983) as expanded this August [52 FR 31852 (August 24, 1987)].

Paragraph (m) includes a definition of what constitutes a formaldehyde health hazard for purposes of the hazard communication provisions. A formaldehyde health hazard is "formaldehyde gas, all mixtures or solutions composed of greater than 0.1 percent formaldehyde, and all materials capable of releasing formaldehyde into the air under any normal condition of use at concentrations reaching or exceeding 0.1 ppm." The use of this definition is intended to help employers identify those workplace conditions involving formaldehyde that require them to provide their employees with hazard information. The inclusion of this definition of a formaldehyde health hazard effectively indicates that levels, forms, and conditions below which the Agency believes formaldehyde exposures to constitute insubstantial or *de minimis* health hazards. In addition, for purposes of hazard determination, the final standard specifies that the hazard communication program address, at a minimum, the following formaldehyde hazards: cancer, irritation and sensitization of the skin and respiratory system, eye and throat irritation, and acute toxicity (see paragraph (m)(1)(ii)).

The hazard communication provisions of the final standard are consistent both with section 6(b)(7) of the Act (which prescribes the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed) and with the requirements of 29 CFR 1910.1200, OSHA's generic Hazard Communication standard, which requires that chemical manufacturers and importers assess the hazards of the chemicals they produce or import.

According to the generic Hazard Communication standard, employers are required to provide information to their employees concerning the hazards of chemicals used in the workplace.

Chemical hazard information is to be transmitted to employees " * * * by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, material safety data sheets and employee training" [§ 1910.1200(a)(1)].

OSHA's provisions for formaldehyde clarify and supplement the generic Hazard Communication Standard. The formaldehyde standard and this preamble are intended to provide specific guidance to employers on the types of information they should include so that they can be assured of complying with both standards. Employers who have been meeting all of their obligations with regard to formaldehyde under the generic hazard communication standard should incur little or no additional burden under the formaldehyde standard.

In the formaldehyde standard, the precise intent of a few words is critical to the correct interpretation of the hazard communication provisions. As in the Hazard Communication standard, mixture means any combination of two or more chemicals if the combination is not, in whole or in part, the result of a chemical reaction. Material is any physical substance that occupies space; the use of this term is not confined to cloth or other fabric. A solution is a homogeneous molecular mixture, usually a liquid, produced by dispersing one or more liquid, gaseous, or solid substance into another to form a homogeneous mixture.

Like the proposal, the final standard contains a requirement that employers affix warning labels to all containers that present a potential health hazard from exposure to formaldehyde; however, the final rule clarifies that a label must be affixed only when it is reasonable to expect that the formaldehyde product being labeled is contributing to an exposure situation that constitutes a health hazard, as defined in paragraph (m)(1)(i). The minimum amount of information required on the label is specified in paragraph (m)(3)(ii), and a provision on substitute warning labels that is identical to that in the proposal is included in paragraph (m)(3)(iii).

In addition, the final standard deletes the proposed exemption from labeling requirements for certain formaldehyde-treated products or containers. As discussed above, the final rule also does not include a specific exemption from scope and application, as was proposed, for formaldehyde solutions containing less than 0.1 percent formaldehyde or for solids incapable of releasing formaldehyde into the workplace air.

OSHA believes that the final rule's use of the definition of a formaldehyde health hazard (adopted from hazard communication) will provide employers with the guidance they need to determine when they need to provide their employees with the required hazard communication program. Consequently, it became unnecessary to exempt specific products. If these products do not pose a health hazard, they do not require a label, nor does any other product that may legitimately have also warranted an exemption by virtue of the low levels of formaldehyde released. OSHA believes this treatment of products is more equitable than the original proposal.

In the proposal, OSHA would have revoked the exemption from Hazard Communication for laboratories that permitted such employers to be in compliance with hazard communication by ensuring that labels on incoming containers remain intact, by maintaining MSDSs for employee use, and by apprising employees of the hazards of chemicals in their workplace. After completing its review of formaldehyde use, OSHA has determined that there are no unique situations in laboratories that use formaldehyde that indicate the general Hazard Communication provisions concerning laboratories should not apply in the final rule being promulgated. Thus, the exemption was restored and laboratory employers will not incur new obligations (except possibly for annual training) for hazard communication.

The record evidence for each of the final rule's hazard communication provisions is discussed below. Like the generic standard, the hazard communication provisions of this standard require only that containers of hazardous materials be labeled. As defined in Hazard Communication [29 CFR 1910.1200, 48 FR 53341, 52 FR 31878], a container means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purpose of communicating hazards, pipes or piping systems are not considered to be containers. OSHA's intent in using the word "container" in the formaldehyde standard is identical to the intent expressed in the Hazard Communication standard, and it represents neither an increase nor decrease in obligation from that expressed in the generic standard.

There was widespread support in the record for the inclusion of hazard communication requirements in the final rule [Exs. 77-12; 77-31; 80-65; 80-74; 80-78; 80-88; 80-257; 86-17; 89; 105A; Tr 5/5/86, pp. 102-103, pp. 126-27; Tr. 5/14/

86, p. 180]. A statement by Dr. Teitelbaum of the Denver Clinic Medical Centers reflects the views of these participants:

* * * I support * * * the principles and details of the [proposed] hazard communication requirements. They offer the best hope of educating and informing employees about the hazards of the materials with which they work [Tr. 5/5/86, p. 125].

However, some participants argued that the existence of OSHA's generic Hazard Communication standard made separate hazard communication provisions in the final rule unnecessary [Exs. 77-2, Attach. 2; 77-9; 77-16; 77-17; 77-18; 77-19A; 77-20; 77-21, Attach. 1; 77-23; 77-24; 77-28; 80-26; 80-30; 80-58; 80-60; 80-64; 80-66; 80-67; 80-76; 80-78; 80-86; 80-261; 80-303; 201-8; Tr. 5/13/86, p. 62] or that downstream employers did not need to have MSDSs available [Ex. 80-40]. For example, the Formaldehyde Institute submitted a post-hearing comment reiterating the Institute's position that OSHA should address hazard communication through the generic standard rather than through a substance-specific standard like the final rule for formaldehyde [Ex. 201-8, p. 46].

OSHA believes that the record evidence provides ample testimony of the difficulties in precisely determining the circumstances under which the generic standard would apply for substances that do not exactly fit the definition of an article yet also do not have very much exposure potential. Without the benefit of a complete standard, which requires employers to determine their employees' exposures, OSHA could define such trivial amounts only within the context of a percentage composition. For resins, which decompose to release formaldehyde, this approach is meaningless. However, a workable approach can be derived within the context of this substance-specific standard and this is the approach that OSHA has taken in the final rule. In addition, as noted above, the final rule's paragraph (m) requirements are entirely consistent with the Agency's generic Hazard Communication standard.

Paragraph (m)(1)(i) of the final rule defines a formaldehyde health hazard and provides employers with guidance as to what constitutes a health hazard for the purpose of hazard communication. There was widespread record support for the adoption of such a performance-oriented approach to defining formaldehyde health hazards and for ensuring that only those employers whose workplaces contain non-trivial amounts of formaldehyde be

required to implement a hazard communication program [Exs. 80-21; 80-54; 80-56; 80-59; 80-61; 80-62; 80-71; 80-72; 80-76; 80-78; 80-79; 80-80; 80-303, Attach. 3; 88-17; 105A; 110A; 170; 172; Tr. 5/15/86, p. 12]. For example, Clare Sullivan of the UPIU stated that the basis for deciding that a solid should be exempted from the final standard's hazard communication requirements should be that the solid cannot produce an "exposure that could result in a health effect" [Ex. 172]. James N. Jardin, Vice President of Armstrong World Industries, a company that manufactures interior furnishings, stated that, in his opinion, hazard communication requirements should be based on the chance for exposure and should not cover materials where only trivial amounts of formaldehyde exist [Ex. 80-21; p. 1]. The HMPA's Technical Director, William Groah, stated that certain articles, such as those containing chemical materials and mixtures in "essentially reacted, cured, dried, absorbed, or encapsulated form," should be exempted from the final rule's hazard communication requirements [Ex. 80-56, pp. 8-9]. The Formaldehyde Institute stressed that the hazard communication provisions should be performance-oriented, because "the performance-oriented approach is the best way to deal with the myriad applications of formaldehyde and to keep up to date with scientific data" [Ex. 80-71, pp. 24-31, 35].

OSHA agrees with the reasoning of these commenters and has decided that the clearest and most efficient way of dealing with the issue of *de minimis* exemptions, and percentage exclusions, is to define what conditions the Agency considers to be a formaldehyde health hazard. The Agency believes that this definition, which is included as paragraph (m)(1)(i) and is used in many of the final rule's hazard communication requirements will eliminate any possible confusion on the part of employers about what forms of formaldehyde and conditions of use will trigger the need for a workplace hazard communication program.

Many commenters endorsed the proposed exemption for liquids and requested that a similar exemption be extended to solids [Exs. 80-54; 80-56; 80-63; 80-78; 80-79; 139; 160, 164; Tr. 5/13/86, p. 73] and to other products [Exs. 80-59; 80-67; 80-69; 80-303, Attach. 1; 80-303, Attach. 3]. For example, several representatives of the wood products industry asked that wood products be exempted from the final rule's hazard communication standard provisions on the grounds that the Agency's generic

Hazard Communication and exempt such products [Exs. 80-5; 80-24; 80-26; 80-34; 80-41; 166]. Paragraph (b)(6)(iii) of the generic Hazard Communication standard specifically exempts wood and wood products from coverage. The reasons given for this exemption were the unmistakable identity of and well-known hazards characteristic of these products. The Hazard Communication standard's preamble also concluded that pesticides impregnated in the wood would be covered by the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Thus, the wood itself would be covered by the wood products exclusion in OSHA's hazard communication standard, while the pesticide would be covered by the labeling exclusion provided for FIFRA-regulated pesticides.

The preamble to the Agency's Hazard Communication standard stated, however, that "non-excluded chemicals which are used in conjunction with * * * wood products, or are known to be present as impurities in these materials, are covered by * * * [the hazard communication] Standard" [48 FR 53280, 53289]. Wood products that are capable of emitting formaldehyde (e.g., because of the use of formaldehyde-releasing glue or resin) are not exempted from the requirements of the Hazard Communication standard, since such uses of formaldehyde are not pesticidal. To ensure that employers in the wood-products industry understand their obligations regarding hazard communication and employee training, and to help clarify the obligation to label wood products containing or treated with formaldehyde, OSHA has not incorporated the wood products exclusion (29 CFR 1910.1200(b)(6)(iii)) into the formaldehyde standard.

OSHA believes that the use of the health hazard definitions included in paragraph (m)(1)(i) responds to the concerns of commenters who requested specific exemptions, extension of the proposed exemption for liquids to solids, and exemption of "articles" as defined under the generic Hazard Communication Standard. Employers with workplaces that do not involve formaldehyde gas, or mixtures or solutions composed of 0.1 or greater percent formaldehyde, or materials capable of releasing formaldehyde to such an extent that exposures are at or above 0.1 ppm will not be required by the final rule to implement a hazard communication program. If a solid contains 0.1 percent or greater formaldehyde, it must be labeled, regardless of the amount of

formaldehyde released. On the other hand, employees who are exposed to formaldehyde at airborne concentrations that present a health hazard will have the protection offered by a comprehensive and formaldehyde-specific hazard communication program regardless of the percentage composition of the product.

Labels: The final rule for formaldehyde requires the employer to affix hazard warning labels complying with the requirements of 29 CFR 1910.1200(f) to all containers of substances containing formaldehyde at levels defined as constituting a health hazard, i.e., mixtures or solutions containing formaldehyde at levels greater than 0.1 percent and solids capable of releasing formaldehyde at or above 0.1 ppm. Employers must affix labels appropriate to the formaldehyde hazards associated with their specific product.

In the proposal, OSHA required a single label for all formaldehyde bearing products. In light of the widely divergent percentage compositions in mixtures and the exposures from formaldehyde offgas from solids, OSHA has developed an approach in the final rule that is more tailored to specific products. For example, a manufacturer, distributor, or importer whose product is a concentrated formaldehyde solution, such as formalin, would include information on the label that imparts the following warning:

CAUTION

CONTAINS FORMALDEHYDE

- TOXIC BY INHALATION AND IF SWALLOWED
- IRRITATING TO THE EYES, RESPIRATORY SYSTEM, AND SKIN
- MAY CAUSE SENSITIZATION BY INHALATION OR SKIN CONTACT
- RISK OF SERIOUS DAMAGE TO EYES
- MAY CAUSE CANCER
- REPEATED OR PROLONGED EXPOSURE INCREASES THE RISK

In determining that this information constitutes an appropriate label for formalin, OSHA relied on existing data on the toxic effects of formaldehyde. Clearly the label should state that evidence of cancer exists since formalin solutions contain more than 0.1 percent formaldehyde. Other toxic effects are also present, and they must be indicated because formalin contains more than 1 percent formaldehyde.

Employers whose employees handle very dilute solutions. (e.g., 0.1 to below 1 percent formaldehyde) in such a manner that provides little potential for

splashing into the eyes, would be required only to affix a label to containers imparting the following information:

CAUTION

CONTAINS FORMALDEHYDE

• MAY CAUSE CANCER REPEATED OR PROLONGED EXPOSURE INCREASES THE RISK

This label reflects the cut-offs used for defining hazards in the generic Hazard Communication standard.

Under Hazard Communication, the manufacturer, importer, or distributor is required to affix an appropriate hazard warning to containers of hazardous chemicals leaving the workplace. These employers can ensure that they have met their obligations regarding labeling by affixing a hazard warning to all solids capable of emitting any formaldehyde. In some circumstances, however, it would be virtually impossible for any downstream use to lead to employee exposures in the workplace exceeding 0.1 ppm regardless of the amount of material present (e.g., furniture, products such as buttons or dishes made from molded plastics). If the employer can determine that his or her product falls within such a category, no warning needs to be conveyed. It may nevertheless be difficult for a manufacturer to determine if a downstream employer is using a product in a manner that assures that exposures are below 0.1 ppm. The manufacturer has to try his hardest to provide appropriate information, but the employer is ultimately responsible for the safety and health of workers in his or her own workplace. Thus, if an employer has formaldehyde exposures exceeding 0.1 ppm, it remains the employer's responsibility to ensure that each container of hazardous material in the workplace is labeled, tagged, or marked.

Employers whose workplaces contain materials that are capable of releasing formaldehyde to the extent that airborne concentrations are above 0.1 ppm must ensure that containers of materials contributing to the hazard are labeled with the following information:

CAUTION

RELEASES FORMALDEHYDE

• TOXIC BY INHALATION • IRRITATING TO EYES, RESPIRATORY SYSTEM, AND SKIN • MAY CAUSE SENSITIZATION BY INHALATION OR BY SKIN CONTACT • MAY CAUSE CANCER REPEATED OR PROLONGED EXPOSURE INCREASES THE RISK

This label accords with the Agency's finding that materials capable of releasing airborne formaldehyde at 0.1 ppm or above may constitute a hazard to some exposed employees.

Some commenters argued that the warning labels used on formaldehyde-treated products or containers of formaldehyde should not bear the legend Potential Cancer Hazard [Exs. 80-4; 80-37; 80-38; 80-40; 80-43; 80-57; 80-86; 85-111D; 201-9]. The reason given for these commenters' objections to the inclusion of this hazard information was that, in their view, formaldehyde does not present a cancer hazard and should be regulated only as an irritant. As the Health Effects and Significance of Risk sections of this preamble make clear, OSHA has determined, based on the evidence in the record as a whole, that formaldehyde is a potential carcinogen. Thus the rationale underlying the argument presented by these commenters is not valid, and the Agency would be remiss if it did not list formaldehyde's cancer-causing potential on the warning labels required by the final rule.

In all other respects, the requirements of paragraph (m)(3) are consistent with the generic Hazard Communication standard's labeling requirements. In addition, they respond to suggestions made by commenters who urged, for example, that the labeling requirements should reflect the relative hazard of the product being labeled rather than specifying a single, uniform label for an infinite variety of products and exposures" [Ex. 201-8]. Thus, OSHA believes that the final rule's labeling provisions will play an important part in the comprehensive hazard communication program required by the standard to protect employees in all affected sectors from the hazards of exposure to formaldehyde.

Material Safety Data Sheets: The requirements regarding material safety data sheets (MSDSs) are largely unchanged from those proposed, except that, in the final rule, the hazard communication definition of a health hazard is used to clarify the obligations of employers under the standard. Employers who manufacture or import formaldehyde-containing products that are free of formaldehyde hazards, as defined in paragraph (m)(1)(i), will not be required to develop and update formaldehyde MSDSs. However, employers engaged in the manufacture, importing, or distribution of materials that constitute a health hazard must provide employers purchasing such materials with MSDSs at the time of initial shipment and after an MSDS has been updated. (They are also obligated

to update the MSDSs as needed to adequately reflect new information on toxicity.)

OSHA's Hazard Communication standard (29 CFR 1910.1200) indicates that if the MSDS is not provided with the initial shipment from a manufacturer, importer, or distributor, the purchaser shall obtain one from the manufacturer, importer, or distributor as soon as possible. This provision is especially essential for formaldehyde. It ensures that an employer who has exposures in the workplace above 0.1 ppm because of formaldehyde-releasing materials will be able to obtain an MSDS from a manufacturer who was otherwise unaware that a potential hazard existed in a downstream segment. For example, manufacturers of textile products treated with formaldehyde-releasing resins may not be aware of the quantities of such products or the conditions of storage at distributors or large retail facilities. When a manufacturer, distributor, or importer becomes aware that a material constitutes a health hazard, appropriate hazard warnings must be made.

The final rule that formaldehyde requires employers to comply with the generic Hazard Communication standard as it applies to Material Safety Data Sheets. To assist employers in determining information that must be included in the MSDS, OSHA has included a typical MSDS for formalin in Appendix A. In actual practice, most MSDSs will be more complex. For example, formalin is usually inhibited from breakdown by methanol or other alcohols, which must also be listed. MSDSs for resins used in the wood products industry and in textile finishing may also be complex. The resin itself may be toxic, and it may release other materials (e.g., phenol) with toxicities that differ from that of formaldehyde. Other irritating or sensitizing impurities may also be present. In general, the MSDS for a resin would contain information on the resin itself and any toxic impurities, which would include formaldehyde.

OSHA believes that, taken together, the hazard communication requirements of the final rule will provide employees in the manufacturing and downstream sectors using formaldehyde and products containing or generating formaldehyde with the information they need about the diverse hazards associated with the various forms and uses of formaldehyde. This information, in turn, will enable employees to protect themselves from many of the risks currently associated with exposure to this substance.

Paragraph (n)—Employee Information and Training

Paragraph (n) of the final standard for formaldehyde requires employers to provide training programs to all of their employees who are potentially exposed to a formaldehyde hazard, as defined in the hazard communication paragraph of this standard. The scope and application of paragraph (n) in the final rule have been modified for consistency with the Agency's new definition of what constitutes a formaldehyde hazard (see paragraph (m)(1)(i)). Otherwise, these requirements are similar to those outlined in the Agency's proposal and are consistent with section (6)(b)(7) of the OSH Act as well as with the requirements for employee training imposed by OSHA's generic Hazard Communication standard. Modifications and clarifications made to the information and training requirements in response to record comments and information are explained below.

The final rule requires employers to assure that all employees assigned to workplaces where formaldehyde constitutes a health hazard as defined by the standard participate in the training program required in paragraph (n). A health hazard is defined as formaldehyde gas, all mixtures and solutions composed of greater than 0.1 percent formaldehyde, and all materials capable of releasing formaldehyde into the air under any normal conditions of use at concentrations exceeding 0.1 ppm. Thus, employers having such workplaces are required by the standard to implement a training program for their employees.

Employers must provide affected employees with the required information and training at the time of their initial assignment and whenever a new hazard from formaldehyde occurs. Examples of potential new hazards are substitution of one product for another or one process for another where the new product or process produces new exposures to formaldehyde. If these new exposures are above the action level, employers are required to institute annual training.

Employers are required to provide training at least annually to all employees exposed to formaldehyde at or above the action level of the STEL. This provision is identical to the frequency of training provision in the proposal except that the final rule includes the STEL as well as the action level as a trigger for annual retraining. This change is consistent with OSHA's use of the STEL as a trigger for several of the final rule's provisions, e.g., periodic monitoring, termination of

monitoring, regulated areas, methods of compliance, and medical surveillance.

As noted above, OSHA has revised the coverage of the information and training requirements. The proposal would have required all employees assigned to workplaces covered by the standard to participate in such a program while the final rule limits participation to those employees assigned to workplaces where the presence of formaldehyde constitutes a health hazard. This modification conforms to two important changes in the final standard: clarification of the definition of formaldehyde and, for the purposes of hazard communication, use of a definition of a formaldehyde health hazard (see paragraph (m)(1)(i)). The Agency believes that these two changes will clarify several misinterpretations of the proposal reflected in comments submitted to the record.

For example, Dr. Sidney Shindell, speaking for the AAMA, contended that work in the apparel industry and elsewhere where formaldehyde is present only "in quantities below the level * * * [that will produce] discomfort from its irritant properties presents no hazard to health" [Ex. 77-2, p. 1]. The record evidence clearly demonstrates that exposure at levels below 0.2 ppm can be associated with adverse health effects such as dermatitis and respiratory irritation [Exs. 85-62; 91; 101; Tr. 5/5/86, pp. 138-140; Tr. 5/6/86, p. 55; Tr. 5/12/86, pp. 188-189; Tr. 5/14/86, pp. 194-195; Tr. 5/15/86, p. 107]. It is thus appropriate for the Agency to require training in hazard identification and control for employees exposed at concentrations well below the PELs since some individuals will experience discomfort from formaldehyde exposure at such levels.

The required training program, which is nearly identical to the proposed training program, obliges employers to provide information on the following topics in a clear and easily understood manner:

- The contents of the formaldehyde regulation and the contents of the MSDS;
- The purpose for and description of the medical surveillance program required by this standard (including a description of the potential health hazards associated with formaldehyde exposure and of the accompanying signs and symptoms of such exposure as well as instructions to report immediately to the employer and such suspected signs or symptoms); a description of any operation in the work area where formaldehyde is present and an explanation of the safe work practices

appropriate for limiting exposure in each job;

- The purpose for, proper use of, and limitations of personal protective equipment and clothing;
- Instructions for the handling of spills, emergencies, and clean-up procedures;
- An explanation of the importance of engineering and work practice controls and any necessary instruction in the use of these controls; and
- A review of emergency procedures, including the specific duties or assignments of each employee in the event of an emergency.

In addition, the employer is required to inform all affected employees of the location of written training materials and to make these materials readily accessible to them. This requirement enables employees and their representatives to review these materials as necessary and, in combination with the training program, to understand both employee rights and duties under the formaldehyde standard.

To provide an objective check of compliance with the requirements of this paragraph, the employer must provide, upon request, all materials relating to the training program to the Assistant Secretary and the Director.

Comments from physicians, employee representatives, and industry spokesmen overwhelmingly endorsed the need for comprehensive training programs [Exs. 77-9; 77-12; 77-32; 77-40; 80-88; 86-17; 105A; 176; Tr. 5/5/86, pp. 127; 204-06; Tr. 5/8/86, p. 156; Tr. 5/13/86, pp. 213-14; Tr. 5/14/86, pp. 265-66].

For example, Dr. Silverstein of the UAW expressed strong support for worker training:

* * * workers need regular, periodic training * * * [in] hazard recognition and control [Tr. 5/14/86, p. 265].

Some commenters felt that employers should be required to provide training, at least annually, for all formaldehyde-exposed workers—not simply for those whose exposures are at or above the action level [Exs. 86-18 and 176; Tr. 5/5/86, p. 127; Tr. 5/8/86, p. 118; Tr. 5/13/86, pp. 204-209]. The ACTWU pointed out that most apparel workers, whose exposures are generally below the action level, are unaware of the hazards associated with exposure to formaldehyde and they are unlikely to receive any information about these hazards except during their training because they will not be covered by the standard's other requirements, such as annual medical surveillance and environmental monitoring [Exs. 86-17; 105-A, pp. 17-18]. The ACTWU

considered training only at the time of initial assignment insufficient to educate these employees and took exception to OSHA's explanation in the preamble for the proposed rule, which stated that these workers were unlikely to experience significant exposures:

[I]n the absence of a definitive showing that workers exposed below the Action Level face no significant risk, the Act compels OSHA to assure that these workers receive adequate training too [Ex. 105-A, p. 19].

Similarly, Dr. Daniel Teitelbaum stated that:

Because the standard specifically requires the employer to educate employees to report immediately the development of signs or symptoms of overexposure to formaldehyde, an annual reminder of the nature of these signs and symptoms is needed. This can best be achieved by a brief, required annual training session [Tr. 5/5/86, p. 127].

Section (h) of OSHA's generic Hazard Communication standard (29 CFR 1910.1200) requires employers to provide employees with information and training only at the time of their initial assignment and whenever a new hazard is introduced into their work area. On August 24, 1987, OSHA expanded the scope of the Hazard Communication standard, and it will soon become effective in all industries where workers are exposed to hazardous chemicals; the previous Hazard Communication standard had applied only to workplaces in the manufacturing sector (SIC 20-39). The preamble to the generic standard (48 FR 53312) contains a discussion of the issue of periodic training:

Although OSHA would certainly encourage employers to provide retraining if they wish to, the greatest need for training is prior to initial assignment, and when the hazard changes, requiring the employee to be aware of new procedures or protective measures. Since the employees will always have visual reminders of hazards in the form of labels, and will have ready access to detailed sources of hazard information (the MSDSs), these should serve to reinforce the information provided in initial training and the sessions provided when the hazard changes.

OSHA's decision to require at least annual training for employees exposed at or above the action level or the STEL is based on the potential for adverse health effects, which is greatly increased above 0.5 ppm. Exposures can be decreased by application of good work practices, and employees need to be trained to recognize the signs and symptoms of formaldehyde exposure. In addition, employee obligations in emergencies and their rights to medical surveillance need to be understood. Because exposures can be reduced if

workers are properly trained, ensuring that those employees at greater risk receive ongoing reinforcement regarding their rights and obligations to protect themselves is appropriate.

OSHA considers training to be one of three vital components in a comprehensive hazard communication program. No single one of these elements alone—labels, material safety data sheets, or training—is completely effective in communicating hazards. The reason for including training provisions in the final rule is to establish the minimum information required to enable these programs to function successfully to reduce the potential for workers to suffer illnesses and injury from exposure to formaldehyde in their work environment.

Paragraph (o)—Recordkeeping

Section 8(c)(3) of the Act obligates employers to create and maintain accurate records of employee exposures to potentially toxic substances or harmful physical agents that must be monitored or measured in the workplace. The Act also provides for regulations that permit employee access to such records and that require employees to be notified if they are exposed to toxic substances in excess of permissible exposure limits. Accordingly, paragraph (o) of the final rule requires employers to keep several types of records mandated by this standard. These include records of: (1) Exposure measurements; (2) objective data relied on as the basis for an exemption from the monitoring requirements; (3) medical surveillance; and (4) respirator fit testing. The requirements in this section of the final rule are generally unchanged from those in the proposal.

In accordance with section 8(c)(3) of the Act and consistent with the retention requirements of the Access to Employee Exposure and Medical Records standard, 29 CFR 1910.20, paragraph (o)(1) of the final rule mandates that accurate records be kept to reflect the extent and duration of employee exposure to formaldehyde. Specifically, records must include the following information: (a) Date of the measurement; (b) operation being monitored; (c) methods of sampling and analysis used to measure 8-hour TWA and short-term exposures, and evidence of the accuracy and precision of the methods used; (d) number, duration and time, and results of samples taken; (e) types of protective devices worn; and (f) the names, job classifications, social security numbers, and exposure estimates of the employees whose exposures are represented by the actual

monitoring results. These requirements were modified slightly to accommodate maintaining exposure records on the STEL.

As mandated by section 8(c) of the Act, employees and their representatives must have access to information on their exposure to toxic substances. This information may also be used by OSHA to examine whether the sampling and analytical methods used by the employer conform to the standard's requirements for precision and accuracy, frequency of monitoring, and representative sampling. The employer needs to maintain sufficiently detailed records to be able to demonstrate to OSHA that the exposure monitoring is representative, accurate, and precise.

Several participants voiced objections to the requirement that employers maintain detailed employee exposure records [Exs. 77-2; 80-56; 80-76; 86-7]. Some objected that these requirements were unnecessary, excessively burdensome because of high employee turnover rate in industries such as apparel manufacturing and construction, or inappropriate for employees exposed below the action level [Exs. 77-2; 80-56; 80-76; 86-7]. For example, G. Stewart Boswell, President of the AAMA, requested that employee recordkeeping requirements be limited to those employees working in areas where the formaldehyde level exceeds the PEL. The AAMA also argued that the high turnover rate and large number of workers in the apparel industry make detailed exposure recordkeeping unnecessary and burdensome [Ex. 80-76].

OSHA believes that records of the exposures of all employees exposed to toxic substances should be kept by their employers, without regard to the specific level of exposure or degree of risk associated with such exposures. The Agency believes that this was the intent of the Congress as reflected in section 8(c)(3) of the Act and notes that these recordkeeping requirements are consistent with those in other substance-specific OSHA health standards (asbestos, ethylene oxide, benzene). This issue is thoroughly reviewed in the preamble to OSHA's Access to Employee Exposure and Medical Records standard, 29 CFR 1910.20 (see 45 FR 35212 to 35284). Moreover, these requirements are not unduly burdensome. OSHA has used a performance approach to these requirements and has thus provided employers an opportunity to determine the most cost-effective manner to use to document employee exposure. For

example, an employer may choose to include only the employee's name, social security number, and job title in the personnel file, and the job title may later be cross-referenced to a separate file containing job-specific representative exposure data. Modern recordkeeping methods generally use computers, microfiche, and other data storage systems, as evidenced by the many construction employers and trade associations that keep centralized data bases of employee records. Such centralized intra-industry and intra-trade data bases can overcome many of the recordkeeping problems associated with a high-turnover workforce. In some instances, particularly for small businesses, basic and readily available units such as microcomputers can accommodate the recordkeeping task simply and inexpensively.

Like the proposal, paragraph (o)(2) of the final standard requires employers who rely on objective data to be exempted from the standard's monitoring requirement to maintain records of such data to show that their employees are not exposed to airborne formaldehyde concentrations at or above the action level or STEL. Many participants who agreed that there was a need for recordkeeping requirements for monitoring data objected to the use of objective data to determine whether employees are exposed to formaldehyde below the action level and STEL [Ex. 80-65; Tr. 5/15/86, p. 113]. For example, representatives of the United Paperworkers International Union urged OSHA to eliminate paragraph (o)(2) because the UPIU believes monitoring to be the only valid determination of employee exposure [Ex. 80-65]. OSHA has retained the objective data exemption in the final rule. Requiring the employer to document objective data determinations and retain them should discourage any abuse, since employees and their representatives are permitted access to this information. Access will enable employees and their representatives to ensure that the objective determination is a reasonable one, thus establishing an important balance and encouraging the use of objective determinations only where the data warrant such use. A record of the objective determination also will permit OSHA to determine whether compliance with the standard has been achieved.

Paragraph (o)(3) requires employers to keep an accurate medical record for each employee subject to medical surveillance. Medical records are necessary to aid in the enforcement of the standard and in the development of information regarding the causes and

prevention of illnesses. These records are also vital for the evaluation of the employee's health, since signs and symptoms of irritation, in particular, are subtle and most readily detected by annually reviewing changes in self-administered disease surveys. Dr. Edward Emmett of Johns Hopkins interpreted the wording of the proposal to mean that the employer should actually take possession of the "results of the medical examination and tests from the physician" [Tr. 5/6/86, p. 76]. Dr. Emmett stressed the importance of the confidentiality of the physician-client relationship. OSHA agrees with Dr. Emmett that such confidentiality is essential to the effectiveness of medical surveillance programs. The Agency believes that physicians will conscientiously observe their ethical responsibilities to their patients; however, OSHA holds employers responsible for ensuring that employee medical records are kept and are made available in the event they need to be inspected. In short, OSHA holds employers responsible for complying with the records access standard (29 CFR 1910.20).

Paragraph (o)(4) mandates that employers establish and maintain accurate records concerning the negative-pressure respirator fit testing required by this standard. This record must include: (a) A copy of the protocol selected for respirator fit testing; (b) a copy of the results of any fit testing performed; (c) the size and manufacturer of the types of respirators available for selection; and (d) the date of the most recent fit testing, the name and social security number of the tested employee, and the respirator type and facepiece selected. Records containing this information are necessary to ensure that employers are using the fit test protocol mandated by Appendix E of this standard. The information will also be useful to employers in selecting respirator types for re-testing respirator fit.

OSHA has slightly altered the final standard in response to a comment by Richard Olsen of the Dow Chemical Company.

We believe this section should be revised to state that protocols for the respective fit-test procedures should be available for cross reference purposes [Ex. 80-78, p. 15].

OSHA has no objection to the use of cross-reference procedures that reduce burdensome paperwork and does not require a copy of the testing protocol to be kept in each employee's file. An employer may include a form in each personnel file listing the results of the qualitative fit test and a code that may

be cross-referenced to a master sheet that indicates the details of the protocol and/or type of respirator selected. OSHA believes that this will provide employers with the flexibility desired by Mr. Olsen. As mentioned before, OSHA has adopted a performance approach in the development of this standard and the Agency does not specify particular recordkeeping strategies that must be followed by employers. Instead, the standard provides an opportunity for employers to devise a system suitable to their particular needs.

In paragraph (o)(5), the final standard provides that records be retained for at least the following periods; (a) 30 years for exposure records; (b) duration of employment plus 30 years for medical records; and (c) until replacement by more recent records for respirator fit testing records (or until respirators are no longer in use). These provisions are unchanged from the proposal. Such retention periods are appropriate for several reasons. First, the long latency periods associated with the induction of cancer caused by exposure to a carcinogen may prevent detection of the disease for twenty or more years after the onset of exposure. In light of this, diagnosis of cancer and other diseases in employee is facilitated not only by medical examinations but by present and past exposure data. Second, the retention of records for extended periods of time makes it possible for future evaluation of the standard's effectiveness in protecting employees from occupational exposure to airborne formaldehyde. Finally, the time periods required for retention of exposure records and medical records are consistent with the OSHA records access standard (29 CFR 1910.20).

Paragraph (o)(6) requires employers to permit access to these exposure and medical records by the Assistant Secretary or the Director of NIOSH, the subject employee, former employees, or employee representatives. Dr. James Melius, a member of the NIOSH panel who testified at the hearing, fully supports OSHA's record access policy. Dr. Melius stated:

I think access to those medical records is important * * * The point is * * * that they * * * [need to be] retained over adequate periods of time [Tr. 5/8/86, p. 81].

OSHA has determined that access to these records is necessary to monitor compliance with the standard adequately and to aid NIOSH in fulfilling its responsibilities under the OSH Act. In reference to the access provision, Walter Quanstrom, General

Manager of the Amoco Corporation, commented that:

Paragraph (o)(6)(iii) allows employee access to medical records but does not refer to OSHA's access to records rule in section 1910.20. This might be taken to imply that access rights under the proposed provision differ somewhat from those in the access to records rule. We do not believe that that is the case, and this point can be clarified by simply referring to section 1910.20 in this proposed provision [Ex. 80-46, p.3].

OSHA did not intend the absence of a specific reference to 29 CFR 1910.20 to imply that access rights under this formaldehyde standard are in any way different from those of other OSHA health standards. Accordingly, OSHA has added a specific reference to § 1910.20 to this provision.

Paragraph (p)—Dates

The final rule retains the 60-day effective date included in the proposal. The final standard thus becomes effective 60 days after publication in the Federal Register. OSHA has determined that this interval will afford affected employers sufficient time to become familiar with the contents of the preamble, standard, and appendices.

As noted above, this final rule on occupational exposure to formaldehyde covers formaldehyde exposures in anatomy, histology, and pathology laboratories (see discussion in section on Scope). The Agency has not made a final decision as to whether it would be more appropriate for formaldehyde exposures in other types of laboratories to be covered by this rule or the generic Toxic Substances in Laboratories standard which is nearing completion. To avoid possible start-up costs under this standard which may be superseded by the general laboratory standard shortly, OSHA is extending the compliance date for these laboratories under this standard for all provision, except the requirement to achieve the PELs, until September 1, 1988. Should the Toxic Substances in Laboratories standard not go into effect by September 1, 1988, or should the Agency decide in the Toxic Substances in Laboratories rule to exclude any laboratory from coverage of that rule, those other laboratories not covered by Toxic Substances in Laboratories will be covered by this rule, and appropriate start-up dates are provided.

In addition, the Agency has established delayed start-up dates for several provisions of the final rule, based on evidence submitted to the record demonstrating that compliance with some provisions may require longer times than compliance with other provisions. These dates are based on the

record in this rulemaking and on the Agency's experience with other standards concerning the amount of time required for employers to perform initial employee monitoring for the PEL and STEL, institute medical surveillance programs, implement emergency procedures, and obtain the necessary control equipment to comply with the standard.

The Agency also believes that the 60-day effective date will provide employers sufficient time to implement the provisions of the standard that do not have delayed startup dates. These include regulated areas, respiratory protection, protective equipment and clothing, hygiene protection, housekeeping, emergencies, hazard communication, and recordkeeping. Most employers in all of the affected sectors have already instituted or are in the process of developing programs addressing these requirements.

OSHA believes that the start-up dates set in this standard should be adequate in all but the most unusual situations. If the time period for meeting any of these start-up dates cannot be met for technical reasons, any employer is entitled to petition the Assistant Secretary for a temporary variance under § 6(b)(6)(A) of the Act. However, based on the record evidence on the standard's feasibility, OSHA does not expect that employers will need to use this variance mechanism.

Start-up Dates

The final rule's start-up date for initial monitoring or objective determinations is unchanged from the proposal. The standard allows employers 6 months from the standard's effective date (*i.e.*, 240 days from the date of publication in the Federal Register) to comply with this requirement. Many companies will be required to hire industrial hygiene consultants or make other arrangements to comply with the initial monitoring provision (50 FR 50485). OSHA believes that the six-month start-up date should provide ample time for employers in the affected sectors to take the samples necessary to make such an initial assessment of their exposure situations. This time period is consistent with public comment (see, for example, Ex. 77-32, Att. 1, p. 4).

The NPRM contained a provision permitting exposure measurements representative of employee exposure to formaldehyde taken in the preceding six months to be used to comply with an employer's initial monitoring obligation, providing that the sampling and analytical methods used to take these measurements met the accuracy and confidence levels required by the

standard. In the final rule, this provision has been deleted because it is redundant with the final rule's objective data provision (paragraph (d)(1)(ii) and requirements for initial monitoring. Employers who have been monitoring employees will be able to use any relevant data to determine whether or not they will have to institute routine monitoring in the future. Even if monitoring is required, those who have already identified exposure areas and representative employees will be able to use this information to comply with the initial monitoring requirement, thus greatly simplifying this task.

Paragraph (p)(2)(ii), Medical surveillance start-up date, is, with only minor clarifications, identical to this provision in the proposed rule. The date for the completion of all initial medical surveillance of eligible employees is 6 months from the effective date of the standard. Only one comment specifically addressed the start-up interval needed for compliance with the initial medical surveillance requirements: the Decorative Laminate Section of NEMA reported that some of its members would require approximately 12 to 36 months to implement medical surveillance programs and engineering controls if the PEL is set at 1 ppm [Ex. 77-9]. OSHA believes, however, that 240 days is a more than adequate period of time for employers to arrange to have those of their employees who are exposed above the action level of the STEL evaluated in accordance with the initial medical surveillance requirements. The required medical surveillance program is performance-based and relatively simple and straightforward to carry out. Depending on the responses in the questionnaires, in most cases no physical examination will be necessary. Arrangements to have employees given routine occupational examinations of the type required by the standard can be made quickly and easily in any region of the country.

The emergency program start-up date requires employers to be able to implement emergency action procedures within six months of the standard's effective date. Facilities in most sectors, especially those involving small formaldehyde or relatively low-hazard uses, should be able to comply with this start-up date even sooner, because the complexity of the required plan varies with the degree of potential hazard. However, OSHA recognizes that other industry segments may require the full 240 days to develop and implement the plan. OSHA received no comments addressing this provision.

The final rule provides for a delayed start-up date for the respiratory protection provisions of the final rule. Employers are expected to implement these provisions as soon as possible, but no later than nine months after the effective date of the standard. While there was no provision made for a separate start-up date for the respiratory protection provisions in the proposal, OSHA believes that some allowance should be made in the final rule for this in view of the fact that the PEL is being lowered and it may take employers some time to complete the monitoring mandated in the final rule and to complete the fit testing of those employees needing to wear respirators. It should be noted, however, that the Agency does not intend for this delayed start-up date to be interpreted as permitting employers under any circumstance to expose their employees over the PELs.

The start-up date provisions for engineering and work practice controls remain unchanged. The final rule requires employers to implement any engineering and work practice controls necessitated by the standard as soon as possible, but in no case later than one year from the effective date of the standard. Commenters were divided about that interval was necessary to implement these controls, with some, like the Decorative Laminate Section of the NEMA, estimating that 36 months might be necessary for some of its members to install the controls to reach a 1 ppm PEL level [Ex. 77-9, p. 3], while others, like Dr. Franklin Mirer of the UAW, maintaining that, at least in foundries, controls to reach a level even lower than the TWA concentrations could be implemented within a year [Tr. 5/14/86, p. 229]. However, most commenters [Exs. 77-19A; 80-56; Tr. 5/14/86, p. 75] stated that a one-year period was adequate for the implementation of such controls for most businesses.

OSHA had determined that the record supports the adequacy of a 12-month period after the effective date for installation of engineering controls. This is sufficient for employers in the affected sectors to perform initial monitoring, arrange for any engineering services shown by the monitoring to be necessary, and install equipment. It is particularly important to note that exposures are already close to or below the TWA and STEL in most cases and the necessary controls are therefore already in place or only improvements are needed (see the discussion in the Technological Feasibility section, above). Based on the Agency's

feasibility analysis, comments in the record, and the testimony of expert witnesses at the hearing, OSHA concludes that a 12-month delay in the start-up date for the implementation of any necessary work practice and engineering controls is an adequate period to allow for compliance. Moreover, the Agency believes that most workplaces will not need to install new engineering controls to comply with this standard.

The final standard deletes the proposed start-up date that would have allowed small businesses (defined as those employing 20 or fewer employees) up to 2 years to comply with the engineering and work practice control requirements of the standard (*i.e.*, an additional 12-month period). The proposed delayed effective date for engineering controls was designed to provide regulatory relief for small firms, which might otherwise experience a differential and adverse economic impact as a result of promulgation of the standard.

A few commenters acknowledged that compliance might be more difficult for small companies [Exs. 77-24; 80-56; Tr. 5/13/86, pp. 139-143; Tr. 5/14/86, pp. 77-86]. For example, Levi Strauss & Company, a large manufacturer of apparel, stated:

We believe a reasonable time period should be provided to allow companies to make the modifications necessary to meet * * * a new standard * * * [Ex. 77-24, pp. 5-7].

The Hardwood Plywood Manufacturers Association, whose members account for more than 70 percent of U.S. hardwood plywood production, recommended that the effective date of the standard be one year except for affected small businesses, for whom the date should be two years [Ex. 80-56, Attachment 2, p. 11]. However, neither Levi Strauss nor the HPMa submitted data to support their claims that small businesses would be differentially impacted.

OSHA has determined that deletion of this proposed requirement from the final rule is appropriate. The basis for this decision is that, since the hazards of exposure to formaldehyde depend on the degree of exposure rather than the size of the facility, employees at small facilities are at as great a level of risk as those exposed equally at larger facilities.

In addition, although OSHA requested (50 FR 50486) that interested parties submit information to assist the Agency in its consideration of "what if any regulatory relief is necessary," small businesses in the affected sectors did

not provide evidence of any particular compliance problems that a business might confront because it is small. Specifically, the proposal asked

that commenters requesting any differential regulatory treatment for small businesses describe their proposals in detail and provide evidence to support their contentions that the relief is necessary and the adoption of their proposals would enable small businesses to attain compliance without compromising * * * employee health and safety (50 FR 50486).

OSHA received no-response to this request, although many small businesses in the regulated community did submit comments on other issues [Exs. 77-25; 80-6; 80-77; 80-132; 80-155; 85-111B].

OSHA thus concludes that the proposed delayed start-up date for small businesses was not necessary or appropriate. Accordingly, this proposed provision has been deleted from the final rule.

Appendices

Five appendices have been included in this final standard. These appendices have been included primarily for purposes of information. The information in Appendix A, Substance Technical Guidelines for Formaldehyde, and in Appendix B, Sampling Strategies and Analytical Methods for Formaldehyde, is designed to aid employers in complying with the requirements in the standard. Appendix C, Medical Surveillance Guidelines for Formaldehyde, and Appendix D, the nonmandatory Medical Disease Questionnaire, provide examining physicians with the information necessary to conduct the medical surveillance programs mandated by this standard. Appendix E provides the protocols for quantitative and qualitative fit testing for negative-pressure respirators. Employers are specifically required by the standard's training provision to provide their employees with the information contained in Appendix A. Minor changes have been made in some instances to the appendices in the final rule. These changes have been made to clarify the information presented in the appendices and to respond to comments and data submitted to the record of this rulemaking.

References

The studies, data, information, and comments referenced by exhibit number in the preamble to this final rule are the primary sources on which the Agency's determinations have been based. A complete set of references is available for examination and copying at the

OSHA Technical Data Center, Docket Office, Room N-3672, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

XI. Authority and Signature

Pursuant to section 4(b)(2), 6(b), and 8(c) of the Occupational Safety and Health Act of 1970 (the Act); (29 U.S.C. 653, 655, 657), the Construction Safety Act (40 U.S.C. 333), the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941), the Secretary of Labor's Order No. 9-83 (48 FR 35736), and 29 CFR Part 1911, this final standard hereby replaces the current formaldehyde standard in 29 CFR 1910.1000, Table Z-2, with a new standard, 29 CFR 1910.1048, as set forth below.

The current standard on occupational exposure to formaldehyde in 29 CFR 1910.1000, Table Z-2 will remain in effect until the new regulation contained in this document actually goes into effect. Should the new regulation (29 CFR 1910.1048) be stayed, either judicially or administratively, or should the new regulation not sustain legal challenge under section 6(f) of the Act, the current formaldehyde standard 29 CFR 1910.1000, Table Z-2, will remain in effect. If these circumstances arise, OSHA will of course issue the necessary documents.

In addition, pursuant to section 4(b)(2) of the Act, OSHA has determined that this new standard would be more effective than the corresponding standards now in Subpart B of Part 1910,

and in Parts 1915, 1918, and 1926 of Title 29, Code of Federal Regulations. Therefore, these corresponding standards would be superseded by these changes. This determination, and the application of the new standard to the maritime and construction industries, would be implemented by adding a new paragraph (j) to 1910.19.

List of Subjects in 29 CFR Part 1910

Formaldehyde, Occupational safety and health, Chemicals, Cancer, Health risk-assessment.

(Secs. 4, 6, and 8 of the Occupational Safety and Health Act of 1970, 84 Stat. 1593, 1597, 1599 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order 9-83 (48 FR 35736); 29 CFR Part 1911).

Signed at Washington, DC, this 20th day of November, 1987.

John A. Pendergrass,

Assistant Secretary of Labor.

PART 1910—[AMENDED]

Part 1910 of Title 29 of the Code of Federal Regulations is hereby amended as follows:

Subpart B—[Amended]

1. The Authority citation for Subpart B of Part 1910 continues to read as follows:

Authority: Secs. 4, 6 and 8 of the Occupational Safety and Health Act, 29 U.S.C. 653, 655, 657; Walsh-Healey Act, 29 U.S.C. 35 *et seq.*; Service Contract Act of 1965, 41 U.S.C. 351 *et seq.*; Pub. L. 91-54, 40 U.S.C. 333; Pub. L. 85-742, 33 U.S.C. 941; National

Foundation on Arts and Humanities Act, 20 U.S.C. 951 *et seq.*; Secretary of Labor's Orders 12-71 (36 FR 8754), 8-76 (41 FR 2505), or 9-83 (48 FR 35736); and 29 CFR Part 1911.

2. A new paragraph (j) is added to § 1910.19 to read as follows:

§ 1910.19 Special provisions for air contaminants.

* * * * *

(j) *Formaldehyde.* Section 1910.1048 shall apply to the exposure of every employee to formaldehyde in every employment and place of employment covered by § 1910.12, 1910.13, 1910.14, 1910.15 or 1910.16 in lieu of any different standard on exposure to formaldehyde which would otherwise be applicable by virtue of those sections.

Subpart Z—[Amended]

3. The authority citation for Subpart Z of Part 1910 is amended to add an entry for § 1910.1048 as follows:

Authority: Secs. 6, 8 Occupational Safety and Health Act, 29 U.S.C. 655, 657; Secretary of Labor's Orders 12-71 (36 FR 8754), 8-76 (41 FR 25059), or 9-83 (48 FR 35736) as applicable; and 29 CFR Part 1911. Section 1910.1000 Tables Z-1, Z-2, Z-3 also issued under 5 U.S.C. 553. * * * § 1910.1048 also issued under 29 U.S.C. 653.

* * * * *

§ 1910.1000 [Amended]

4. A footnote "1" is added to the entry "Formaldehyde" in Table Z-2 of § 1910.1000 to read as follows. The entry for "Formaldehyde" is republished.

TABLE Z-2

Material	8-hour time weighted average	Acceptable ceiling concentration	Acceptable maximum peak above the acceptance ceiling concentration for an 8-hour shift	
			Concentration	Maximum duration
Formaldehyde ¹ (ANSI Z-37.16-1967)	3 ppm	5 ppm	10 ppm	30 minutes.

¹ This standard applies to any industry for which § 1910.1048 is stayed or otherwise not in effect.

5. A new § 1910.1048 including Appendices A, B, C, D and E are added to Subpart Z to read as follows:

§ 1910.1048 Formaldehyde.

(a) *Scope and application.* This standard applies to all occupational exposures to formaldehyde, i.e. from formaldehyde gas, its solutions, and materials that release formaldehyde.

(b) *Definitions.* For purposes of this standard, the following definitions shall apply:

"Action level" means a concentration of 0.5 part formaldehyde per million parts of air (0.5 ppm) calculated as an eight (8)-hour time-weighted average (TWA) concentration.

"Assistant Secretary" means the Assistant Secretary of Labor for the

Occupational Safety and Health Administration, U.S. Department of Labor, or designee.

"Authorized Person" means any person required by work duties to be present in regulated areas, or authorized to do so by the employer, by this section, or by the OSH Act of 1970.

"Director" means the Director of the National Institute for Occupational

Safety and Health, U.S. Department of Health and Human Services, or designee.

"Emergency" is any occurrence, such as but not limited to equipment failure, rupture of containers, or failure of control equipment that results in an uncontrolled release of a significant amount of formaldehyde.

"Employee exposure" means the exposure to airborne formaldehyde which would occur without corrections for protection provided by any respirator that is in use.

"Formaldehyde" means the chemical substance, HCHO, Chemical Abstracts Service Registry No. 50-00-0.

(c) *Permissible Exposure Limit (PEL)*—(1) *TWA*. The employer shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds one part formaldehyde per million parts of air (1 ppm) as an 8-hour TWA.

(2) *Short Term Exposure Limit (STEL)*: The employer shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds two parts formaldehyde per million parts of air (2 ppm) as a 15-minute STEL.

(d) *Exposure monitoring*—(1) *General*. (i) Each employer who has a workplace covered by this standard shall monitor employees to determine their exposure to formaldehyde.

(ii) *Exceptions*. (A) The employer need not initiate exposure monitoring unless there is a formaldehyde hazard as defined in paragraph m of this standard or there are employee health complaints possibly associated with formaldehyde exposure.

(B) Where the employer documents, using objective data, that the presence of formaldehyde or formaldehyde-releasing products in the workplace cannot result in airborne concentrations of formaldehyde that would cause any employee to be exposed at or above the action level or the STEL under foreseeable conditions of use, the employer will not be required to measure employee exposure to formaldehyde.

(iii) When an employee's exposure is determined from representative sampling, the measurements used shall be representative of the employee's full shift or short-term exposure to formaldehyde, as appropriate.

(iv) Representative samples for each job classification in each work area shall be taken for each shift unless the employer can document with objective data that exposure levels for a given job classification are equivalent for different work shifts.

(2) *Initial monitoring*. The employer shall identify all employees who may be exposed at or above the action level or at or above the STEL and accurately determine the exposure of each employee so identified.

(i) Unless the employer chooses to measure the exposure of each employee potentially exposed to formaldehyde, the employer shall develop a representative sampling strategy and measure sufficient exposures within each job classification for each workshift to correctly characterize and not underestimate the exposure of any employee within each exposure group.

(ii) The initial monitoring process shall be repeated each time there is a change in production, equipment, process, personnel, or control measures which may result in new or additional exposure to formaldehyde.

(3) *Periodic monitoring*. (i) The employer shall periodically measure and accurately determine exposure to formaldehyde for employees shown by the initial monitoring to be exposed at or above the action level or at or above the STEL.

(ii) If the last monitoring results reveal employee exposure at or above the action level, the employer shall repeat monitoring of the employees at least every 6 months.

(iii) If the last monitoring results reveal employee exposure at or above the STEL, the employer shall repeat monitoring of the employees at least once a year under worst conditions.

(4) *Termination of monitoring*. The employer may discontinue periodic monitoring for employees if results from two consecutive sampling periods taken at least 7 days apart show that employee exposure is below the action level and the STEL. The results must be statistically representative and consistent with the employer's knowledge of the job and work operation.

(5) *Accuracy of monitoring*. Monitoring shall be accurate, at the 95 percent confidence level, to within plus or minus 25 percent for airborne concentrations of formaldehyde at the TWA and the STEL and to within plus or minus 35 percent for airborne concentrations of formaldehyde at the action level.

(6) *Employee notification of monitoring results*. Within 15 days of receiving the results of exposure monitoring conducted under this standard, the employer shall notify the affected employees of these results. Notification shall be in writing, either by distributing copies of the results to the employees or by posting the results. If the employee exposure is over either

PEL, the employer shall develop and implement a written plan to reduce employee exposure to or below both PELs, and give written notice to employees. The written notice shall contain a description of the corrective action being taken by the employer to decrease exposure.

(7) *Observation of monitoring*. (i) The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to formaldehyde required by this standard.

(ii) When observation of the monitoring of employee exposure to formaldehyde requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the clothing and equipment to the observer, require the observer to use such clothing and equipment, and assure that the observer complies with all other applicable safety and health procedures.

(e) *Regulated areas*. (1) The employer shall establish regulated areas where the concentration of airborne formaldehyde exceeds either the TWA or the STEL and post all entrances and accessways with signs bearing the following information:

DANGER

FORMALDEHYDE

IRRITANT AND POTENTIAL CANCER HAZARD

AUTHORIZED PERSONNEL ONLY

(2) The employer shall limit access to regulated areas to authorized persons who have been trained to recognize the hazards of formaldehyde.

(3) An employer at a multiemployer worksite who establishes a regulated area shall communicate the access restrictions and locations of these areas to other employers with work operations at that worksite.

(f) *Methods of compliance*—(1) *Engineering controls and work practices*. The employer shall institute engineering and work practice controls to reduce and maintain employee exposures to formaldehyde at or below the TWA and the STEL.

(2) *Exception*. Whenever the employer has established that feasible engineering and work practice controls cannot reduce employee exposure to or below either of the PELs, the employer shall apply these controls to reduce employee exposures to the extent feasible and shall supplement them with respirators which satisfy this standard.

(g) *Respiratory protection*—(1) *General*. Where respiratory protection is

required, the employer shall provide the respirators at no cost to the employee and shall assure that they are properly used. The respirators shall comply with the requirements of this standard and shall reduce the concentration of formaldehyde inhaled by the employee to at or below both the TWA and the STEL. Respirators shall be used in the following circumstances:

(i) During the interval necessary to install or implement feasible engineering and work practice controls;

(ii) In work operations, such as maintenance and repair activities or vessel cleaning, for which the employer establishes that engineering and work practice controls are not feasible;

(iii) In work situations where feasible engineering and work practice controls

are not yet sufficient to reduce exposure to or below the PELs; and

(iv) In emergencies.

(2) *Respirator selection.* (i) The appropriate respirators as specified in Table 1 shall be selected from those approved by the Mine Safety and Health Administration (MSHA) and by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR Part 11.

(ii) The employer shall make available a powered air purifying respirator, meeting the specifications in Table 1, to any employee who experiences difficulty wearing a negative pressure respirator to reduce exposure to formaldehyde.

(3) *Respirator usage.* (i) Whenever respirator use is required by this

standard, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b), (d), (e), and (f).

(ii) The employer shall perform either quantitative or qualitative face fit tests in accordance with the procedures outlined in Appendix E at the time of initial fitting and at least annually thereafter for all employees required by this standard to wear negative pressure respirators.

(A) Respirators selected shall be from those exhibiting the best facepiece fit.

(B) No respirator shall be chosen that would potentially permit the employee to inhale formaldehyde at concentrations in excess of either the TWA or the STEL.

TABLE 1.—MINIMUM REQUIREMENTS FOR RESPIRATORY PROTECTION AGAINST FORMALDEHYDE

Condition of use or formaldehyde concentration (ppm)	Minimum respirator required ¹
Up to 10 ppm.....	Full facepiece with cartridges or canisters specifically approved for protection against formaldehyde. ²
Up to 100 ppm	Full-face mask, chest or back mounted type, with industrial size canister specifically approved for protection against formaldehyde. Type C supplied air respirator, demand type, with full facepiece, hood, or helmet.
Above 100 ppm or unknown (emergencies).	Self-contained breathing apparatus (SCBA) with positive pressure full facepiece. Combination supplied-air, full facepiece positive pressure respirator with auxiliary self-contained air supply.
Firefighting	SCBA with positive pressure in full face-piece.
Escape	SCBA in demand or pressure demand mode. Full-face mask, front or back mounted type with industrial size canister specifically approved for protection against formaldehyde.

¹ Respirators specified for use at higher concentrations may be used at lower concentrations.

² A half-mask respirator with cartridges specifically approved for protection against formaldehyde can be substituted for the full facepiece respirator providing that effective gas-proof goggles are provided and used in combination with the half-mask respirator.

(iii) Where air purifying chemical cartridge respirators are used, the cartridges shall be replaced after three hours of use or at the end of the workshift, whichever is sooner unless the cartridge contains a NIOSH-approved end-of-service indicator to show when breakthrough occurs.

(iv) Unless the canister contains a NIOSH-approved end-of service-life indicator to show when breakthrough occurs, canisters used in atmospheres up to 10 ppm shall be replaced every 4 hours and industrial sized canisters used in atmospheres up to 100 ppm shall be replaced every two hours or at the end of the workshift, whichever is sooner.

(v) Employers shall permit employees to leave the work area to wash their faces and respirator facepieces as

needed to prevent skin irritation from respirator use.

(h) *Protective equipment and clothing.* Employers shall comply with the provisions of 29 CFR 1910.132 and 29 CFR 1910.133. When protective equipment or clothing is provided under these provisions, the employer shall provide these protective devices at no cost to the employee and assure that the employee wears them.

(1) *Selection.* The employer shall select protective clothing and equipment based upon the form of formaldehyde to be encountered, the conditions of use, and the hazard to be prevented.

(i) All contact of the eyes and skin with liquids containing 1 percent or more formaldehyde shall be prevented by the use of chemical protective clothing made of material impervious to formaldehyde and the use of other

personal protective equipment, such as goggles and face shields, as appropriate to the operation.

(ii) Contact with irritating or sensitizing materials shall be prevented to the extent necessary to eliminate the hazard.

(iii) Where a face shield is worn, chemical safety goggles are also required if there is a danger of formaldehyde reaching the area of the eye.

(iv) Full body protection shall be worn for entry into areas where concentrations exceed 100 ppm and for emergency reentry into areas of unknown concentration.

(2) *Maintenance of protective equipment and clothing.* (i) The employer shall assure that protective equipment and clothing that has become

contaminated with formaldehyde is cleaned or laundered before its reuse.

(ii) When ventilating formaldehyde-contaminated clothing and equipment, the employer shall establish a storage area so that employee exposure is minimized. Containers for contaminated clothing and equipment and storage areas shall have labels and signs containing the following information:

DANGER

FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT

AVOID INHALATION AND SKIN CONTACT

(iii) The employer shall assure that only persons trained to recognize the hazards of formaldehyde remove the contaminated material from the storage area for purposes of cleaning, laundering, or disposal.

(iv) The employer shall assure that no employee takes home equipment or clothing that is contaminated with formaldehyde.

(v) The employer shall repair or replace all required protective clothing and equipment for each affected employee as necessary to assure its effectiveness.

(vi) The employer shall inform any person who launders, cleans, or repairs such clothing or equipment of formaldehyde's potentially harmful effects and of procedures to safely handle the clothing and equipment.

(i) *Hygiene protection.* (1) The employer shall provide change rooms, as described in 29 CFR 1910.141 for employees who are required to change from work clothing into protective clothing to prevent skin contact with formaldehyde.

(2) If employees' skin may become splashed with solutions containing 1 percent or greater formaldehyde, for example because of equipment failure or improper work practices, the employer shall provide conveniently located quick drench showers and assure that affected employees use these facilities immediately.

(3) If there is any possibility that an employee's eyes may be splashed with solutions containing 0.1 percent or greater formaldehyde, the employer shall provide acceptable eyewash facilities within the immediate work area for emergency use.

(j) *Housekeeping.* For operations involving formaldehyde liquids or gas, the employer shall conduct a program to detect leaks and spills, including regular visual inspections.

(1) Preventative maintenance of equipment, including surveys for leaks, shall be undertaken at regular intervals.

(2) In work areas where spillage may occur, the employer shall make provisions to contain the spill, to decontaminate the work area, and to dispose of the waste.

(3) The employer shall assure that all leaks are repaired and spills are cleaned promptly by employees wearing suitable protective equipment and trained in proper methods for cleanup and decontamination.

(4) Formaldehyde-contaminated waste and debris resulting from leaks or spills shall be placed for disposal in sealed containers bearing a label warning of formaldehyde's presence and of the hazards associated with formaldehyde.

(k) *Emergencies.* For each workplace where there is the possibility of an emergency involving formaldehyde, the employer shall assure appropriate procedures are adopted to minimize injury and loss of life. Appropriate procedures shall be implemented in the event of an emergency.

(l) *Medical surveillance—(1)*

Employees covered. (i) The employer shall institute medical surveillance programs for all employees exposed to formaldehyde at concentrations at or exceeding the action level or exceeding the STEL.

(ii) The employer shall make medical surveillance available for employees who develop signs and symptoms of overexposure to formaldehyde and for all employees exposed to formaldehyde in emergencies. When determining whether an employee may be experiencing signs and symptoms of possible overexposure to formaldehyde, the employer may rely on the evidence that signs and symptoms associated with formaldehyde exposure will occur only in exceptional circumstances when airborne exposure is less than 0.1 ppm and when formaldehyde is present in materials in concentrations less than 0.1 percent.

(2) *Examination by a physician.* All medical procedures, including administration of medical disease questionnaires, shall be performed by or under the supervision of a licensed physician and shall be provided without cost to the employee, without loss of pay, and at a reasonable time and place.

(3) *Medical disease questionnaire.* The employer shall make the following medical surveillance available to employees prior to assignment to a job where formaldehyde exposure is at or above the action level or above the STEL and annually thereafter. The employer shall also make the following medical surveillance available promptly upon determining that an employee is experiencing signs and symptoms

indicative of possible overexposure to formaldehyde.

(i) Administration of a medical disease questionnaire, such as in Appendix D, which is designed to elicit information on work history, smoking history, any evidence of eye, nose, or throat irritation; chronic airway problems or hyperreactive airway disease; allergic skin conditions or dermatitis; and upper or lower respiratory problems.

(ii) A determination by the physician, based on evaluation of the medical disease questionnaire, of whether a medical examination is necessary for employees not required to wear respirators to reduce exposure to formaldehyde.

(4) *Medical examinations.* Medical examinations shall be given to any employee who the physician feels, based on information in the medical disease questionnaire, may be at increased risk from exposure to formaldehyde and at the time of initial assignment and at least annually thereafter to all employees required to wear a respirator to reduce exposure to formaldehyde. The medical examination shall include:

(i) A physical examination with emphasis on evidence of irritation or sensitization of the skin and respiratory system, shortness of breath, or irritation of the eyes.

(ii) Laboratory examinations for respirator wearers consisting of baseline and annual pulmonary function tests. As a minimum, these tests shall consist of forced vital capacity (FVC), forced expiratory volume in one second (FEV1), and forced expiratory flow (FEF).

(iii) Any other test which the examining physician deems necessary to complete the written opinion.

(iv) Counseling of employees having medical conditions that would be directly or indirectly aggravated by exposure to formaldehyde on the increased risk of impairment of their health.

(5) *Examinations for employees exposed in an emergency.* The employer shall make medical examinations available as soon as possible to all employees who have been exposed to formaldehyde in an emergency.

(i) The examination shall include a medical and work history with emphasis on any evidence of upper or lower respiratory problems, allergic conditions, skin reaction or hypersensitivity, and any evidence of eye, nose, or throat irritation.

(ii) Other examinations shall consist of those elements considered appropriate by the examining physician.

(6) *Information provided to the physician.* The employer shall provide the following information to the examining physician:

- (i) A copy of this standard and Appendices A, C, D, and E;
 - (ii) A description of the affected employee's job duties as they relate to the employee's exposure to formaldehyde;
 - (iii) The representative exposure level for the employee's job assignment;
 - (iv) Information concerning any personal protective equipment and respiratory protection used or to be used by the employee; and
 - (v) Information from previous medical examinations of the affected employee within the control of the employer.
- (vi) In the event of a nonroutine examination because of an emergency, the employer shall provide to the physician as soon as possible: a description of how the emergency occurred and the exposure the victim may have received.

(7) *Physician's written opinion.* (i) For each examination required under this standard, the employer shall obtain a written opinion from the examining physician. This written opinion shall contain the results of the medical examination except that it shall not reveal specific findings or diagnoses unrelated to occupational exposure to formaldehyde. The written opinion shall include:

(A) The physician's opinion as to whether the employee has any medical condition that would place the employee at an increased risk of material impairment of health from exposure to formaldehyde;

(B) Any recommended limitations on the employee's exposure or changes in the use of personal protective equipment, including respirators;

(C) A statement that the employee has been informed by the physician of any medical conditions which would be aggravated by exposure to formaldehyde, whether these conditions may have resulted from past formaldehyde exposure or from exposure in an emergency, and whether there is a need for further examination or treatment.

(ii) The employer shall provide for retention of the results of the medical examination and tests conducted by the physician.

(iii) The employer shall provide a copy of the physician's written opinion to the affected employee within 15 days of its receipt.

(m) *Hazard communication*—(1) *General.* Notwithstanding any exemption granted in 29 CFR 1910.1200(b)(6)(iii) for wood products,

each employer who has a workplace covered by this standard shall comply with the requirements of 29 CFR 1910.1200(e)–(j).

(i) For purposes of hazard communication, formaldehyde gas, all mixtures or solutions composed of greater than 0.1 percent formaldehyde, and materials capable of releasing formaldehyde into the air under any normal condition of use at concentrations reaching or exceeding 0.1 ppm shall be considered a health hazard.

(ii) As a minimum, specific health hazards that the employer shall address are: cancer, irritation and sensitization of the skin and respiratory system, eye and throat irritation, and acute toxicity.

(2) Manufacturers and importers who produce or import formaldehyde or formaldehyde containing products shall provide downstream employers using or handling these products with an objective determination through the required labels and MSDSs if these items may constitute a health hazard within the meaning of 29 CFR 1910.1200(d) under normal conditions of use.

(3) *Labels.* (i) The employer shall assure that hazard warning labels complying with the requirements of 29 CFR 1910.1200(f) are affixed to all containers where the presence of formaldehyde constitutes a health hazard.

(ii) *Information on labels.* As a minimum, labels shall identify the hazardous chemical; list the name and address of the responsible party; contain the information "Potential Cancer Hazard"; and appropriately warn of all other hazards as defined in 29 CFR 1910.1200, Appendices A and B.

(iii) *Substitute warning labels.* The employer may use warning labels required by other statutes, regulations, or ordinances which impart the same information as the warning statements required by this paragraph.

(4) *Material safety data sheets.* (i) Any employer who uses formaldehyde-containing materials that constitute a health hazard as defined in this standard shall comply with the requirements of 29 CFR 1910.1200(g) with regard to the development and updating of Material Safety Data Sheets.

(ii) Manufacturers, importers, and distributors of formaldehyde containing materials that constitute a health hazard as defined in this standard shall assure that Material Safety Data Sheets and updated information are provided to all employers purchasing such materials at the time of the initial shipment and at the time of the first shipment after a Material Safety Data Sheet is updated.

(n) *Employee information and training*—(1) *Participation.* The employer shall assure that all employees who are assigned to workplaces where there is a health hazard from formaldehyde participate in a training program.

(2) *Frequency.* (i) Employers shall provide employees with information and training on formaldehyde at the time of their initial assignment and whenever a new hazard from formaldehyde is introduced into their work area.

(ii) Employers shall provide such information and training at least annually for all employees exposed to formaldehyde concentrations at or above the action level or the STEL.

(3) *Training program.* The training program shall be conducted in a manner which the employee is able to understand and shall include:

(i) A discussion of the contents of this regulation and the contents of the Material Safety Data Sheet.

(ii) The purpose for and a description of the medical surveillance program required by this standard, including:

(A) A description of the potential health hazards associated with exposure to formaldehyde and a description of the signs and symptoms of exposure to formaldehyde.

(B) Instructions to immediately report to the employer the development of any adverse signs or symptoms that the employee suspects is attributable to formaldehyde exposure.

(iii) Description of operations in the work area where formaldehyde is present and an explanation of the safe work practices appropriate for limiting exposure to formaldehyde in each job;

(iv) The purpose for, proper use of, and limitations of personal protective clothing and equipment;

(v) Instructions for the handling of spills, emergencies, and clean-up procedures;

(vi) An explanation of the importance of engineering and work practice controls for employee protection and any necessary instruction in the use of these controls; and

(vii) A review of emergency procedures including the specific duties or assignments of each employee in the event of an emergency.

(4) *Access to training materials.* (i) The employer shall inform all affected employees of the location of written training materials and shall make these materials readily available, without cost, to the affected employees.

(ii) The employer shall provide, upon request, all training materials relating to the employee training program to the Assistant Secretary and the Director.

(o) *Recordkeeping*—(1) *Exposure measurements*. The employer shall establish and maintain an accurate record of all measurements taken to monitor employee exposure to formaldehyde. This record shall include:

- (i) The date of measurement;
- (ii) The operation being monitored;
- (iii) The methods of sampling and analysis and evidence of their accuracy and precision;

- (iv) The number, durations, time, and results of samples taken;

- (v) The types of protective devices worn; and

- (vi) The names, job classifications, social security numbers, and exposure estimates of the employees whose exposures are represented by the actual monitoring results.

(2) *Exposure determinations*. Where the employer has determined that no monitoring is required under this standard, the employer shall maintain a record of the objective data relied upon to support the determination that no employee is exposed to formaldehyde at or above the action level.

(3) *Medical surveillance*. The employer shall establish and maintain an accurate record for each employee subject to medical surveillance under this standard. This record shall include:

- (i) The name and social security number of the employee;

- (ii) The physician's written opinion;

- (iii) A list of any employee health complaints that may be related to exposure to formaldehyde.

- (iv) A copy of the medical examination results, including medical disease questionnaires and results of any medical tests required by the standard or mandated by the examining physician.

(4) *Respirator fit testing*. (i) The employer shall establish and maintain accurate records for employees subject to negative pressure respirator fit testing required by this standard.

- (ii) This record shall include:

- (A) A copy of the protocol selected for respirator fit testing.

- (B) A copy of the results of any fit testing performed.

- (C) The size and manufacturer of the types of respirators available for selection.

- (D) The date of the most recent fit testing, the name and social security number of each tested employee, and the respirator type and facepiece selected.

(5) *Record retention*. The employer shall retain records required by this standard for at least the following periods:

- (i) Exposure records and determinations shall be kept for at least 30 years.

- (ii) Medical records shall be kept for the duration of employment plus 30 years.

- (iii) Respirator fit testing records shall be kept until replaced by a more recent record.

(6) *Availability of records*. (i) Upon request, the employer shall make all records maintained as a requirement of this standard available for examination and copying to the Assistant Secretary and the Director.

- (ii) The employer shall make employee exposure records, including estimates made from representative monitoring and available upon request for examination, and copying to the subject employee, or former employee, and employee representatives in accordance with 29 CFR 1910.20(a)–(e) and (g)–(i).

- (iii) Employee medical records required by this standard shall be provided upon request for examination and copying, to the subject employee or former employee or to anyone having the specific written consent of the subject employee or former employee.

(p) *Dates*—(1) *Effective dates*—(i) *General*. This section shall become effective February 2, 1988, except as noted below.

- (ii) *Laboratories*. This standard shall become effective for anatomy, histology, and pathology laboratories February 2, 1988, except as noted in the start-up date section. For all other laboratories, paragraphs (a) and (c) of this standard shall become effective February 2, 1988, and paragraphs (b) and (d)–(o) of this standard shall become effective on September 1, 1988 except as noted in the start-up date section.

- (2) *Start-up dates*—(i) *Exposure determinations*. Initial monitoring or objective determinations that no monitoring is required by the standard shall be completed by 6 months after the effective date of the standard.

- (ii) *Medical surveillance*. The initial medical surveillance or all eligible employees shall be completed by 6 months after the effective date of the standard.

- (iii) *Emergencies*. The emergency procedures required by this standard shall be implemented by 6 months after the effective date of the standard.

- (iv) *Respiratory protection*. Respiratory protection as required in this standard shall be provided as soon as possible and no later than 9 months after the effective date of the standard.

- (v) *Engineering and work practice controls*. Engineering and work practice controls required by this standard shall

be implemented as soon as possible, but no later than one year after the effective date of this standard.

Appendix A to § 1910.1048—Substance Technical Guidelines for Formalin

The following Substance Technical Guideline for Formalin provides information on uninhibited formalin solution (37% formaldehyde, no methanol stabilizer). It is designed to inform employees at the production level of their rights and duties under the formaldehyde standard whether their job title defines them as workers or supervisors. Much of the information provided is general; however, some information is specific for formalin. When employee exposure to formaldehyde is from resins capable of releasing formaldehyde, the resin itself and other impurities or decomposition products may also be toxic, and employers should include this information as well when informing employees of the hazards associated with the materials they handle. The precise hazards associated with exposure to formaldehyde depend both on the form (solid, liquid, or gas) of the material and the concentration of formaldehyde present. For example, 37–50 percent solutions of formaldehyde present a much greater hazard to the skin and eyes from spills or splashes than solutions containing less than 1 percent formaldehyde. Individual Substance Technical Guidelines used by the employer for training employees should be modified to properly give information on the material actually being used.

Substance Identification

Chemical Name: Formaldehyde

Chemical Family: Aldehyde

Chemical Formula: HCHO

Molecular Weight: 30.03

Chemical Abstracts Service Number (CAS Number): 50–00–0

Synonyms: Formalin; Formic Aldehyde; Paraform; Formol; Formalin (Methanol-free); Fyde; Formalith; Methanal; Methyl Aldehyde; Methylene Glycol; Methylene Oxide; Tetraoxymethalene; Oxomethane; Oxymethylene

Components and Contaminants

Percent: 37.0 Formaldehyde

Percent: 63.0 Water

(Note.—Inhibited solutions contain methanol.)

Other Contaminants: Formic acid (alcohol free)

Exposure Limits:

OSHA TWA—1 ppm

OSHA STEL—2 ppm

Physical Data

Description: Colorless liquid, pungent odor

Boiling point: 214 °F (101 °C)

Specific Gravity: 1.08 (H₂O=1 @ 20 °C)

pH: 2.8-4.0

Solubility in Water: Miscible

Solvent Solubility: Soluble in alcohol and acetone

Vapor Density: 1.04 (Air=1 @ 20 °C)

Odor Threshold: 0.8-1 ppm

Fire and Explosion Hazard

Moderate fire and explosion hazard when exposed to heat or flame.

The flash point of 37% formaldehyde solutions is above normal room temperature, but the explosion range is very wide, from 7 to 73% by volume in air.

Reaction of formaldehyde with nitrogen dioxide, nitromethane, perchloric acid and aniline, or peroxyformic acid yields explosive compounds.

Flash Point: 185 °F (85 °C) closed cup

Lower Explosion Limit: 7%

Upper Explosion Limit: 73%

Autoignition Temperature: 806 °F (430 °C)

Flammability Class (OSHA): III A

Extinguishing Media: Use dry chemical, "alcohol foam", carbon dioxide, or water in flooding amounts as fog. Solid streams may not be effective. Cool fire-exposed containers with water from side until well after fire is out.

Use of water spray to flush spills can also dilute the spill to produce nonflammable mixtures. Water runoff, however, should be contained for treatment.

National Fire Protection Association Section 325M Designation:

Health: 2—Materials hazardous to health, but areas may be entered with full-faced mask self-contained breathing apparatus which provides eye protection.

Flammability: 2—Materials which must be moderately heated before ignition will occur. Water spray may be used to extinguish the fire because the material can be cooled below its flash point.

Reactivity: D—Materials which (in themselves) are normally stable even under fire exposure conditions and which are not reactive with water. Normal fire fighting procedures may be used.

Reactivity

Stability: Formaldehyde solutions may self-polymerize to form paraformaldehyde which precipitates.

Incompatibility (Materials to Avoid):

Strong oxidizing agents, caustics, strong alkalis, isocyanates, anhydrides, oxides, and inorganic acids.

Formaldehyde reacts with hydrochloric acid to form the potent carcinogen, bis-chloromethyl ether. Formaldehyde

reacts with nitrogen dioxide, nitromethane, perchloric acid and aniline, or peroxyformic acid to yield explosive compounds. A violent reaction occurs when formaldehyde is mixed with strong oxidizers.

Hazardous Combustion or Decomposition Products: Oxygen from the air can oxidize formaldehyde to formic acid, especially when heated. Formic acid is corrosive.

Health Hazard Data

Acute Effects of Exposure

Ingestion (Swallowing): Liquids containing 10 to 40% formaldehyde cause severe irritation and inflammation of the mouth, throat, and stomach. Severe stomach pains will follow ingestion with possible loss of consciousness and death. Ingestion of dilute formaldehyde solutions (0.03-0.04%) may cause discomfort in the stomach and pharynx.

Inhalation (Breathing): Formaldehyde is highly irritating to the upper respiratory tract and eyes. Concentrations of 0.5 to 2.0 ppm may irritate the eyes, nose, and throat of some individuals. Concentrations of 3 to 5 ppm also cause tearing of the eyes and are intolerable to some persons. Concentrations of 10 to 20 ppm cause difficulty in breathing, burning of the nose and throat, cough, and heavy tearing of the eyes, and 25 to 30 ppm causes severe respiratory tract injury leading to pulmonary edema and pneumonitis. A concentration of 100 ppm is immediately dangerous to life and health. Deaths from accidental exposure to high concentrations of formaldehyde have been reported.

Skin (Dermal): Formalin is a severe skin irritant and a sensitizer. Contact with formalin causes white discoloration, smarting, drying, cracking, and scaling. Prolonged and repeated contact can cause numbness and a hardening or tanning of the skin. Previously exposed persons may react to future exposure with an allergic eczematous dermatitis or hives.

Eye Contact: Formaldehyde solutions splashed in the eye can cause injuries ranging from transient discomfort to severe, permanent corneal clouding and loss of vision. The severity of the effect depends on the concentration of formaldehyde in the solution and whether or not the eyes are flushed with water immediately after the accident.

Note.—The perception of formaldehyde by odor and eye irritation becomes less sensitive with time as one adapts to formaldehyde. This can lead to overexposure if a worker is relying on formaldehyde's warning properties to alert him or her to the potential for exposure.

Acute Animal Toxicity:

Oral, rats: LD50=800 mg/kg

Oral, mouse: LD50=42 mg/kg

Inhalation, rats: LCLo=250 mg/kg

Inhalation, mouse: LCLo=900 mg/kg

Inhalation, rats: LC50=590 mg/kg

Chronic Effects of Exposure

Carcinogenicity: Formaldehyde has the potential to cause cancer in humans. Repeated and prolonged exposure increases the risk. Various animal experiments have conclusively shown formaldehyde to be a carcinogen in rats. In humans, formaldehyde exposure has been associated with cancers of the lung, nasopharynx and oropharynx, and nasal passages.

Mutagenicity: Formaldehyde is genotoxic in several *in vitro* test systems showing properties of both an initiator and a promoter.

Toxicity: Prolonged or repeated exposure to formaldehyde may result in respiratory impairment. Rats exposed to formaldehyde at 2 ppm developed benign nasal tumors and changes of the cell structure in the nose as well as inflamed mucous membranes of the nose. Structural changes in the epithelial cells in the human nose have also been observed. Some persons have developed asthma or bronchitis following exposure to formaldehyde, most often as the result of an accidental spill involving a single exposure to a high concentration of formaldehyde.

Emergency and First Aid Procedures

Ingestion (Swallowing): If the victim is conscious, dilute, inactivate, or absorb the ingested formaldehyde by giving milk, activated charcoal, or water. Any organic material will inactivate formaldehyde. Keep affected person warm and at rest. Get medical attention immediately. If vomiting occurs, keep head lower than hips.

Inhalation (Breathing): Remove the victim from the exposure area to fresh air immediately. Where the formaldehyde concentration may be very high, each rescuer must put on a self-contained breathing apparatus before attempting to remove the victim, and medical personnel should be informed of the formaldehyde exposure immediately. If breathing has stopped, give artificial respiration. Keep the affected person warm and at rest. Qualified first-aid or medical personnel should administer oxygen, if available, and maintain the patient's airways and blood pressure until the victim can be transported to a medical facility. If exposure results in a highly irritated upper respiratory tract and coughing continues for more than 10 minutes, the

worker should be hospitalized for observation and treatment.

Skin Contact: Remove contaminated clothing (including shoes) immediately. Wash the affected area of your body with soap or mild detergent and large amounts of water until no evidence of the chemical remains (at least 15 to 20 minutes). If there are chemical burns, get first aid to cover the area with sterile, dry dressing, and bandages. Get medical attention if you experience appreciable eye or respiratory irritation.

Eye Contact: Wash the eyes immediately with large amounts of water occasionally lifting lower and upper lids, until no evidence of chemical remains (at least 15 to 20 minutes). In case of burns, apply sterile bandages loosely without medication. Get medical attention immediately. If you have experienced appreciable eye irritation from a splash or excessive exposure, you should be referred promptly to an ophthalmologist for evaluation.

Emergency Procedures

Emergencies: If you work in an area where a large amount of formaldehyde could be released in an accident or from equipment failure, your employer must develop procedures to be followed in event of an emergency. You should be trained in your specific duties in the event of an emergency, and it is important that you clearly understand these duties. Emergency equipment must be accessible and you should be trained to use any equipment that you might need. Formaldehyde contaminated equipment must be cleaned before reuse.

If a spill of appreciable quantity occurs, leave the area quickly unless you have specific emergency duties. Do not touch spilled material. Designated persons may stop the leak and shut off ignition sources if these procedures can be done without risk. Designated persons should isolate the hazard area and deny entry except for necessary people protected by suitable protective clothing and respirators adequate for the exposure. Use water spray to reduce vapors. Do not smoke, and prohibit all flames or flares in the hazard area.

Special Firefighting Procedures: Learn procedures and responsibilities in the event of a fire in your workplace. Become familiar with the appropriate equipment and supplies and their location. In firefighting, withdraw immediately in case of rising sound from venting safety device or any discoloration of storage tank due to fire.

Spill, Leak, and Disposal Procedures

Occupational Spill: For small containers, place the leaking container

in a well ventilated area. Take up small spills with absorbent material and place the waste into properly labeled containers for later disposal. For larger spills, dike the spill to minimize contamination and facilitate salvage or disposal. You may be able to neutralize the spill with sodium hydroxide or sodium sulfite. Your employer must comply with EPA rules regarding the clean-up of toxic waste and notify state and local authorities, if required. If the spill is greater than 1,000 lb/day, it is reportable under EPA's Superfund legislation.

Waste Disposal: Your employer must dispose of waste containing formaldehyde in accordance with applicable local, state, and Federal law and in a manner that minimizes exposure of employees at the site and of the clean-up crew.

Monitoring and Measurement Procedures

Monitoring Requirements: If your exposure to formaldehyde exceeds the 0.5 ppm action level or the 2 ppm STEL, your employer must monitor your exposure. Your employer need not measure every exposure if a "high exposure" employee can be identified. This person usually spends the greatest amount of time nearest the process equipment. If you are a "representative employee", you will be asked to wear a sampling device to collect formaldehyde. This device may be a passive badge, a sorbent tube attached to a pump, or an impinger containing liquid. You should perform your work as usual, but inform the person who is conducting the monitoring of any difficulties you are having wearing the device.

Evaluation of 8-hour Exposure: Measurements taken for the purpose of determining time-weighted average (TWA) exposures are best taken with samples covering the full shift. Samples collected must be taken from the employee's breathing zone air.

Short-term Exposure Evaluation: If there are tasks that involve brief but intense exposure to formaldehyde, employee exposure must be measured to assure compliance with the STEL. Sample collections are for brief periods, only 15 minutes, but several samples may be needed to identify the peak exposure.

Monitoring Techniques: OSHA's only requirement for selecting a method for sampling and analysis is that the methods used accurately evaluate the concentration of formaldehyde in employees' breathing zones. Sampling and analysis may be performed by collection of formaldehyde on liquid or

solid sorbents with subsequent chemical analysis. Sampling and analysis may also be performed by passive diffusion monitors and short-term exposure may be measured by instruments such as real-time continuous monitoring systems and portable direct reading instruments.

Notification of Results: Your employer must inform you of the results of exposure monitoring representative of your job. You may be informed in writing, but posting the results where you have ready access to them constitutes compliance with the standard.

Protective Equipment and Clothing

[Material impervious to formaldehyde is needed if the employee handles formaldehyde solutions of 1% or more. Other employees may also require protective clothing or equipment to prevent dermatitis.]

Respiratory Protection: Use NIOSH-approved full facepiece negative pressure respirators equipped with approved cartridges or canisters within the use limitations of these devices. (Present restrictions on cartridges and canisters do not permit them to be used for a full workshift.) In all other situations, use positive pressure respirators such as the positive-pressure air purifying respirator or the self-contained breathing apparatus (SCBA). If you use a negative pressure respirator, your employer must provide you with fit testing of the respirator at least once a year in accordance with the procedures outlined in Appendix E.

Protective Gloves: Wear protective (impervious) gloves provided by your employer, at no cost, to prevent contact with formalin. Your employer should select these gloves based on the results of permeation testing and in accordance with the ACGIH Guidelines for Selection of Chemical Protective Clothing.

Eye Protection: If you might be splashed in the eyes with formalin, it is essential that you wear goggles or some other type of complete protection for the eye. You may also need a face shield if your face is likely to be splashed with formalin, but you must not substitute face shields for eye protection. (This section pertains to formaldehyde solutions of 1% or more.)

Other Protective Equipment: You must wear protective (impervious) clothing and equipment provided by your employer at no cost to prevent repeated or prolonged contact with formaldehyde liquids. If you are required to change into whole-body chemical protective clothing, your employer must provide a

change room for your privacy and for storage of your normal clothing.

If you are splashed with formaldehyde, use the emergency showers and eyewash fountains provided by your employer immediately to prevent serious injury. Report the incident to your supervisor and obtain necessary medical support.

Entry Into an IDLH Atmosphere

Enter areas where the formaldehyde concentration might be 100 ppm or more only with complete body protection including a self-contained breathing apparatus with a full facepiece operated in a positive pressure mode or a supplied air respirator with full facepiece and operated in a positive pressure mode. This equipment is essential to protect your life and health under such extreme conditions.

Engineering Controls

Ventilation is the most widely applied engineering control method for reducing the concentration of airborne substances in the breathing zones of workers. There are two distinct types of ventilation.

Local Exhaust: Local exhaust ventilation is designed to capture airborne contaminants as near to the point of generation as possible. To protect you, the direction of contaminant flow must always be toward the local exhaust system inlet and away from you.

General (Mechanical): General dilution ventilation involves continuous introduction of fresh air into the workroom to mix with the contaminated air and lower your breathing zone concentration of formaldehyde. Effectiveness depends on the number of air changes per hour. Where devices emitting formaldehyde are spread out over a large area, general dilution ventilation may be the only practical method of control.

Work Practices: Work practices and administrative procedures are an important part of a control system. If you are asked to perform a task in a certain manner to limit your exposure to formaldehyde, it is extremely important that you follow these procedures.

Medical Surveillance

Medical surveillance helps to protect employees' health. You are encouraged strongly to participate in the medical surveillance program.

Your employer must make a medical surveillance program available at no expense to you and at a reasonable time and place if you are exposed to formaldehyde at concentrations above 0.5 ppm as an 8-hour average or 2 ppm

over any 15-minute period. You will be offered medical surveillance at the time of your initial assignment and once a year afterward as long as your exposure is at least 0.5 ppm (TWA) or 2 ppm (STEL). Even if your exposure is below these levels, you should inform your employer if you have signs and symptoms that you suspect, through your training, are related to your formaldehyde exposure because you may need medical surveillance to determine if your health is being impaired by your exposure.

The surveillance plan includes:

(a) A medical disease questionnaire.

(b) A physical examination if the physician determines this is necessary.

If you are required to wear a respirator, your employer must offer you a physical examination and a pulmonary function test every year.

The physician must collect all information needed to determine if you are at increased risk from your exposure to formaldehyde. At the physician's discretion, the medical examination may include other tests, such as a chest x-ray, to make this determination.

After a medical examination the physician will provide your employer with a written opinion which includes any special protective measures recommended and any restrictions on your exposure. The physician must inform you of any medical conditions you have which would be aggravated by exposure to formaldehyde.

All records from your medical examinations, including disease surveys, must be retained at your employer's expense.

Emergencies

If you are exposed to formaldehyde in an emergency and develop signs or symptoms associated with acute toxicity from formaldehyde exposure, your employer must provide you with a medical examination as soon as possible. This medical examination will include all steps necessary to stabilize your health. You may be kept in the hospital for observation if your symptoms are severe to ensure that any delayed effects are recognized and treated.

Appendix B to § 1910.1048—Sampling Strategy and Analytical Methods for Formaldehyde

To protect the health of employees, exposure measurements must be unbiased and representative of employee exposure. The proper measurement of employee exposure requires more than a token commitment on the part of the employer. OSHA's mandatory requirements establish a

baseline; under the best of circumstances all questions regarding employee exposure will be answered. Many employers, however, will wish to conduct more extensive monitoring before undertaking expensive commitments, such as engineering controls, to assure that the modifications are truly necessary. The following sampling strategy, which was developed at NIOSH by Nelson A. Leidel, Kenneth A. Busch, and Jeremiah R. Lynch and described in NIOSH publication No. 77-173 (Occupational Exposure Sampling Strategy Manual) will assist the employer in developing a strategy for determining the exposure of his or her employees.

There is no one correct way to determine employee exposure. Obviously, measuring the exposure of every employee exposed to formaldehyde will provide the most information on any given day. Where few employees are exposed, this may be a practical solution. For most employers, however, use of the following strategy will give just as much information at less cost.

Exposure data collected on a single day will not automatically guarantee the employer that his or her workplace is always in compliance with the formaldehyde standard. This does not imply, however, that it is impossible for an employer to be sure that his or her worksite is in compliance with the standard. Indeed, a properly designed sampling strategy showing that all employees are exposed below the PELs, at least with a 95 percent certainty, is compelling evidence that the exposure limits are being achieved provided that measurements are conducted using valid sampling strategy and approved analytical methods.

There are two PELs, the TWA concentration and the STEL. Most employers will find that one of these two limits is more critical in the control of their operations, and OSHA expects that the employer will concentrate monitoring efforts on the critical component. If the more difficult exposure is controlled, this information, along with calculations to support the assumptions, should be adequate to show that the other exposure limit is also being achieved.

Sampling Strategy

Determination of the Need for Exposure Measurements

The employer must determine whether employees may be exposed to concentrations in excess of the action level. This determination becomes the

first step in an employee exposure monitoring program that minimizes employer sampling burdens while providing adequate employee protection. If employees may be exposed above the action level, the employer must measure exposure. Otherwise, an objective determination that employee exposure is low provides adequate evidence that exposure potential has been examined.

The employer should examine all available relevant information, *eg.* insurance company and trade association data and information from suppliers or exposure data collected from similar operations. The employer may also use previously-conducted sampling including area monitoring. The employer must make a determination relevant to each operation although this need not be on a separate piece of paper. If the employer can demonstrate conclusively that no employee is exposed above the action level or the STEL through the use of objective data, the employer need proceed no further on employee exposure monitoring until such time that conditions have changed and the determination is no longer valid.

If the employer cannot determine that employee exposure is less than the action level and the STEL, employee exposure monitoring will have to be conducted.

Workplace Material Survey

The primary purpose of a survey of raw material is to determine if formaldehyde is being used in the work environment and if so, the conditions under which formaldehyde is being used.

The first step is to tabulate all situations where formaldehyde is used in a manner such that it may be released into the workplace atmosphere or contaminate the skin. This information should be available through analysis of company records and information on the MSDSs available through provisions of this standard and the Hazard Communication standard.

If there is an indication from materials handling records and accompanying MSDSs that formaldehyde is being used in the following types of processes or work operations, there may be a potential for releasing formaldehyde into the workplace atmosphere:

(1) Any operation that involves grinding, sanding, sawing, cutting, crushing, screening, sieving, or any other manipulation of material that generates formaldehyde-bearing dust

(2) Any processes where there have been employee complaints or symptoms indicative of exposure to formaldehyde

(3) Any liquid or spray process involving formaldehyde

(4) Any process that uses formaldehyde in preserved tissue

(5) Any process that involves the heating of a formaldehyde-bearing resin. Processes and work operations that use formaldehyde in these manners will probably require further investigation at the worksite to determine the extent of employee monitoring that should be conducted.

Workplace Observations

To this point, the only intention has been to provide an indication as to the existence of potentially exposed employees. With this information, a visit to the workplace is needed to observe work operations, to identify potential health hazards, and to determine whether any employees may be exposed to hazardous concentrations of formaldehyde.

In many circumstances, sources of formaldehyde can be identified through the sense of smell. However, this method of detection should be used with caution because of olfactory fatigue.

Employee location in relation to source of formaldehyde is important in determining if an employee may be significantly exposed to formaldehyde. In most instances, the closer a worker is to the source, the higher the probability that a significant exposure will occur.

Other characteristics should be considered. Certain high temperature operations give rise to higher evaporation rates. Locations of open doors and windows provide natural ventilation that tend to dilute formaldehyde emissions. General room ventilation also provides a measure of control.

Calculation of Potential Exposure Concentrations

By knowing the ventilation rate in a workplace and the quantity of formaldehyde generated, the employer may be able to determine by calculation if the PELs might be exceeded. To account for poor mixing of formaldehyde into the entire room, locations of fans and proximity of employees to the work operation, the employer must include a safety factor. If an employee is relatively close to a source, particularly if he or she is located downwind, a safety factor of 100 may be necessary. For other situations, a factor of 10 may be acceptable. If the employer can demonstrate through such calculations that employee exposure does not exceed the action level or the STEL, the employer may use this information as objective data to

demonstrate compliance with the standard.

Sampling Strategy

Once the employer determines that there is a possibility of substantial employee exposure to formaldehyde, the employer is obligated to measure employee exposure.

The next step is selection of a maximum risk employee. When there are different processes where employees may be exposed to formaldehyde, a maximum risk employee should be selected for each work operation.

Selection of the maximum risk employee requires professional judgment. The best procedure for selecting the maximum risk employee is to observe employees and select the person closest to the source of formaldehyde. Employee mobility may affect this selection; *eg.* if the closest employee is mobile in his tasks, he may not be the maximum risk employee. Air movement patterns and differences in work habits will also affect selection of the maximum risk employee.

When many employees perform essentially the same task, a maximum risk employee cannot be selected. In this circumstance, it is necessary to resort to random sampling of the group of workers. The objective is to select a subgroup of adequate size so that there is a high probability that the random sample will contain at least one worker with high exposure if one exists. The number of persons in the group influences the number that need to be sampled to ensure that at least one individual from the highest 10 percent exposure group is contained in the sample. For example, to have 90 percent confidence in the results, if the group size is 10, nine should be sampled; for 50, only 18 need to be sampled.

If measurement shows exposure to formaldehyde at or above the action level or the STEL, the employer needs to identify all other employees who may be exposed at or above the action level or STEL and measure or otherwise accurately characterize the exposure of these employees.

Whether representative monitoring or random sampling are conducted, the purpose remains the same—to determine if the exposure of any employee is above the action level. If the exposure of the most exposed employee is less than the action level and the STEL, regardless of how the employee is identified, then it is reasonable to assume that measurements of exposure of the other employees in that operation would be below the action level and the STEL.

Exposure Measurements

There is no "best" measurement strategy for all situations. Some elements to consider in developing a strategy are:

- (1) Availability and cost of sampling equipment
- (2) Availability and cost of analytical facilities
- (3) Availability and cost of personnel to take samples
- (4) Location of employees and work operations
- (5) Intraday and interday variations in the process
- (6) Precision and accuracy of sampling and analytical methods, and
- (7) Number of samples needed.

Samples taken for determining compliance with the STEL differ from those that measure the TWA concentration in important ways. STEL samples are best taken in a nonrandom fashion using all available knowledge relating to the area, the individual, and the process to obtain samples during periods of maximum expected concentrations. At least three measurements on a shift are generally needed to spot gross errors or mistakes; however, only the highest value represents the STEL.

If an operation remains constant throughout the workshift, a much greater number of samples would need to be taken over the 32 discrete nonoverlapping periods in an 8-hour workshift to verify compliance with a STEL. If employee exposure is truly uniform throughout the workshift, however, an employer in compliance with the 1 ppm TWA would be in compliance with the 2 ppm STEL, and this determination can probably be made using objective data.

Need to Repeat the Monitoring Strategy

Interday and intraday fluctuations in employee exposure are mostly influenced by the physical processes that generate formaldehyde and the work habits of the employee. Hence, in-plant process variations influence the employer's determination of whether or not additional controls need to be imposed. Measurements that employee exposure is low on a day that is not representative of worst conditions may not provide sufficient information to determine whether or not additional engineering controls should be installed to achieve the PELs.

The person responsible for conducting sampling must be aware of systematic changes which will negate the validity of the sampling results. Systematic changes in formaldehyde exposure

concentration for an employee can occur due to:

- (1) The employee changing patterns of movement in the workplace
 - (2) Closing of plant doors and windows
 - (3) Changes in ventilation from season to season
 - (4) Decreases in ventilation efficiency or abrupt failure of engineering control equipment
 - (5) Changes in the production process or work habits of the employee.
- Any of these changes, if they may result in additional exposure that reaches the next level of action (*i.e.* 0.5 or 1.0 ppm as an 8-hr average or 2 ppm over 15 minutes) require the employer to perform additional monitoring to reassess employee exposure.

A number of methods are suitable for measuring employee exposure to formaldehyde or for characterizing emissions within the worksite. The preamble to this standard describes some methods that have been widely used or subjected to validation testing. A detailed analytical procedure derived from the OSHA Method 52 for acrolein and formaldehyde is presented below for informational purposes.

Inclusion of OSHA's method in this appendix in no way implies that it is the only acceptable way to measure employee exposure to formaldehyde. Other methods that are free from significant interferences and that can determine formaldehyde at the permissible exposure limits within ± 25 percent of the "true" value at the 95 percent confidence level are also acceptable. Where applicable, the method should also be capable of measuring formaldehyde at the action level to ± 35 percent of the "true" value with a 95 percent confidence level. OSHA encourages employers to choose methods that will be best for their individual needs. The employer must exercise caution, however, in choosing an appropriate method since some techniques suffer from interferences that are likely to be present in workplaces of certain industry sectors where formaldehyde is used.

OSHA's Analytical Laboratory Method

Method No: 52

Matrix: Air

Target Concentration: 1 ppm (1.2 mg/m³)

Procedures: Air samples are collected by drawing known volumes of air through sampling tubes containing XAD-2 adsorbent which have been coated with 2-(hydroxymethyl) piperidine. The samples are desorbed with toluene and then analyzed by gas

chromatography using a nitrogen selective detector.

Recommended Sampling Rate and Air Volumes: 0.1 L/min and 24 L

Reliable Quantitation Limit: 16 ppb (20 µg/m³)

Standard Error of Estimate at the Target Concentration: 7.3%

Status of the Method: A sampling and analytical method that has been subjected to the established evaluation procedures of the Organic Methods Evaluation Branch.

Date: March 1985

1. General Discussion

1.1 Background: The current OSHA method for collecting acrolein vapor recommends the use of activated 13X molecular sieves. The samples must be stored in an ice bath during and after sampling and also they must be analyzed within 48 hours of collection. The current OSHA method for collecting formaldehyde vapor recommends the use of bubblers containing 10% methanol in water as the trapping solution.

This work was undertaken to resolve the sample stability problems associated with acrolein and also to eliminate the need to use bubblers to sample formaldehyde. A goal of this work was to develop and/or to evaluate a common sampling and analytical procedure for acrolein and formaldehyde.

NIOSH has developed independent methodologies for acrolein and formaldehyde which recommend the use of reagent-coated adsorbent tubes to collect the aldehydes as stable derivatives. The formaldehyde sampling tubes contain Chromosorb 102 adsorbent coated with N-benzylethanolamine (BEA) which reacts with formaldehyde vapor to form a stable oxazolidine compound. The acrolein sampling tubes contain XAD-2 adsorbent coated with 2-(hydroxymethyl)piperidine (2-HMP) which reacts with acrolein vapor to form a different, stable oxazolidine derivative. Acrolein does not appear to react with BEA to give a suitable reaction product. Therefore, the formaldehyde procedure cannot provide a common method for both aldehydes. However, formaldehyde does react with 2-HMP to form a very suitable reaction product. It is the quantitative reaction of acrolein and formaldehyde with 2-HMP that provides the basis for this evaluation.

This sampling and analytical procedure is very similar to the method recommended by NIOSH for acrolein. Some changes in the NIOSH methodology were necessary to permit the simultaneous determination of both

aldehydes and also to accommodate OSHA laboratory equipment and analytical techniques.

1.2 Limit-defining parameters: The analyte air concentrations reported in this method are based on the recommended air volume for each analyte collected separately and a desorption volume of 1 mL. The amounts are presented as acrolein and/or formaldehyde, even though the derivatives are the actual species analyzed.

1.2.1 Detection limits of the analytical procedure: The detection limit of the analytical procedure was 386 pg per injection for formaldehyde. This was the amount of analyte which gave a peak whose height was about five times the height of the peak given by the residual formaldehyde derivative in a typical blank front section of the recommended sampling tube.

1.2.2 Detection limits of the overall procedure: The detection limits of the overall procedure were 482 ng per sample (16 ppb or 20 $\mu\text{g}/\text{m}^3$ for formaldehyde). This was the amount of analyte spiked on the sampling device which allowed recoveries approximately equal to the detection limit of the analytical procedure.

1.2.3 Reliable quantitation limits: The reliable quantitation limit was 482 ng per sample (16 ppb or 20 $\mu\text{g}/\text{m}^3$) for formaldehyde. These were the smallest amounts of analyte which could be quantitated within the limits of a recovery of at least 75% and a precision (± 1.96 SD) of $\pm 25\%$ or better.

The reliable quantitation limit and detection limits reported in the method are based upon optimization of the instrument for the smallest possible amount of analyte. When the target concentration of an analyte is exceptionally higher than these limits, they may not be attainable at the routine operating parameters.

1.2.4 Sensitivity: The sensitivity of the analytical procedure over concentration ranges representing 0.4 to 2 times the target concentration, based on the recommended air volumes, was 7,589 area units per $\mu\text{g}/\text{mL}$ for formaldehyde. This value was determined from the slope of the calibration curve. The sensitivity may vary with the particular instrument used in the analysis.

1.2.5 Recovery: The recovery of formaldehyde from samples used in an 18-day storage test remained above 92% when the samples were stored at ambient temperature. These values were determined from regression lines which

were calculated from the storage data. The recovery of the analyte from the collection device must be at least 75% following storage.

1.2.6 Precision (analytical method only): The pooled coefficient of variation obtained from replicate determinations of analytical standards over the range of 0.4 to 2 times the target concentration was 0.0052 for formaldehyde (Section 4.3).

1.2.7 Precision (overall procedure): The precision at the 95% confidence level for the ambient temperature storage tests was $\pm 14.3\%$ for formaldehyde. These values each include an additional $\pm 5\%$ for sampling error. The overall procedure must provide results at the target concentrations that are $\pm 25\%$ at the 95% confidence level.

1.2.8 Reproducibility: Samples collected from controlled test atmospheres and a draft copy of this procedure were given to a chemist unassociated with this evaluation. The formaldehyde samples were analyzed following 15 days storage. The average recovery was 96.3% and the standard deviation was 1.7%.

1.3 Advantages:

1.3.1 The sampling and analytical procedures permit the simultaneous determination of acrolein and formaldehyde.

1.3.2 Samples are stable following storage at ambient temperature for at least 18 days.

1.4 Disadvantages: None.

2. Sampling Procedure

2.1 Apparatus:

2.1.1 Samples are collected by use of a personal sampling pump that can be calibrated to within $\pm 5\%$ of the recommended 0.1 L/min sampling rate with the sampling tube in line.

2.1.2 Samples are collected with laboratory prepared sampling tubes. The sampling tube is constructed of silane treated glass and is about 8-cm long. The ID is 4 mm and the OD is 6 mm. One end of the tube is tapered so that a glass wool end plug will hold the contents of the tube in place during sampling. The other end of the sampling tube is open to its full 4-mm ID to facilitate packing of the tube. Both ends of the tube are fire-polished for safety. The tube is packed with a 75-mg backup section, located nearest the tapered end and a 150-mg sampling section of pretreated XAD-2 adsorbent which has been coated with 2-HMP. The two sections of coated adsorbent are separated and retained with small plugs of silanized glass wool. Following packing, the sampling tubes are sealed with two $\frac{3}{32}$ inch OD plastic end caps. Instructions for the

pretreatment and the coating of XAD-2 adsorbent are presented in Section 4 of this method.

2.1.3 Sampling tubes, similar to those recommended in this method, are marketed by Supelco, Inc. These tubes were not available when this work was initiated; therefore, they were not evaluated.

2.2 Reagents: None required.

2.3 Technique:

2.3.1 Properly label the sampling tube before sampling and then remove the plastic end caps.

2.3.2 Attach the sampling tube to the pump using a section of flexible plastic tubing such that the large, front section of the sampling tube is exposed directly to the atmosphere. Do not place any tubing ahead of the sampling tube. The sampling tube should be attached in the worker's breathing zone in a vertical manner such that it does not impede work performance.

2.3.3 After sampling for the appropriate time, remove the sampling tube from the pump and then seal the tube with plastic end caps.

2.3.4 Include at least one blank for each sampling set. The blank should be handled in the same manner as the samples with the exception that air is not drawn through it.

2.3.5 List any potential interferences on the sample data sheet.

2.4 Breakthrough:

2.4.1 Breakthrough was defined as the relative amount of analyte found on a backup sample in relation to the total amount of analyte collected on the sampling train.

2.4.2 For formaldehyde collected from test atmospheres containing 6 times the PEL, the average 5% breakthrough air volume was 41 L. The sampling rate was 0.1 L/min and the average mass of formaldehyde collected was 250 μg .

2.5 Desorption Efficiency: No desorption efficiency corrections are necessary to compute air sample results because analytical standards are prepared using coated adsorbent. Desorption efficiencies were determined, however, to investigate the recoveries of the analytes from the sampling device. The average recovery over the range of 0.4 to 2 times the target concentration, based on the recommended air volumes, was 96.2% for formaldehyde. Desorption efficiencies were essentially constant over the ranges studied.

2.6 Recommended Air Volume and Sampling Rate:

2.6.1 The recommended air volume for formaldehyde is 24 L.

2.6.2. The recommended sampling rate is 01. L/min.

2.7. *Interferences:*

2.7.1 Any collected substance that is capable of reacting 2-HMP and thereby depleting the derivatizing agent is a potential interference. Chemicals which contain a carbonyl group, such as acetone, may be capable of reacting with 2-HMP.

2.7.2 There are no other known interferences to the sampling method.

2.8 *Safety Precautions:*

2.8.1 Attach the sampling equipment to the worker in such a manner that it will not interfere with work performance or safety.

2.8.2 Follow all safety practices that apply to the work area being sampled.

3. Analytical Procedure

3.1 *Apparatus:*

3.1.1 A gas chromatograph (GC), equipped with a nitrogen selective detector. A Hewlett-Packard Model 5840A GC fitted with a nitrogen-phosphorus flame ionization detector (NPD) was used for this evaluation. Injections were performed using a Hewlett-Packard Model 7671A automatic sampler.

3.1.2 A GC column capable of resolving the analytes from any interference. A 6 ft x 1/4 in OD (2mm ID) glass GC column containing 10% UCON 50-HB-5100 + 2% KOH on 80/100 mesh Chromosorb W-AW was used for the evaluation. Injections were performed on-column.

3.1.3 Vials, glass 2-mL with Teflon-lined caps.

3.1.4 Volumetric flasks, pipets, and syringes for preparing standards, making dilutions, and performing injections.

3.2 *Reagents:*

3.2.1 Toluene and dimethylformamide. Burdick and Jackson solvents were used in this evaluation.

3.2.2 Helium, hydrogen, and air, GC grade.

3.2.3 Formaldehyde, 37%, by weight, in water. Aldrich Chemical, ACS Reagent Grade formaldehyde was used in this evaluation.

3.2.4 Amberlite XAD-2 adsorbent coated with 2-(hydroxymethyl)-piperidine (2-HMP), 10% by weight (Section 4).

3.2.5 Desorbing solution with internal standard. This solution was prepared by adding 20 µL of dimethylformamide to 100 mL of toluene.

3.3 *Standard preparation:*

3.3.1 *Formaldehyde:* Prepare stock standards by diluting known volumes of 37% formaldehyde solution with methanol. A procedure to determine the

formaldehyde content of these standards is presented in Section 4. A standard containing 7.7 mg/mL formaldehyde was prepared by diluting 1 mL of the 37% reagent to 50 mL with methanol.

3.3.2 It is recommended that analytical standards be prepared about 16 hours before the air samples are to be analyzed in order to ensure the complete reaction of the analytes with 2-HMP. However, rate studies have shown the reaction to be greater than 95% complete after 4 hours. Therefore, one or two standards can be analyzed after this reduced time if sample results are outside the concentration range of the prepared standards.

3.3.3 Place 150-mg portions of coated XAD-2 adsorbent, from the same lot number as used to collect the air samples, into each of several glass 2-mL vials. Seal each vial with a Teflon-lined cap.

3.3.4 Prepare fresh analytical standards each day by injecting appropriate amounts of the diluted analyte directly onto 150-mg portions of coated adsorbent. It is permissible to inject both acrolein and formaldehyde on the same adsorbent portion. Allow the standards to stand at room temperature. A standard, approximately the target levels, was prepared by injecting 11 µL of the acrolein and 12 µL of the formaldehyde stock standards onto a single coated XAD-2 adsorbent portion.

3.3.5 Prepare a sufficient number of standards to generate the calibration curves. Analytical standard concentrations should bracket sample concentrations. Thus, if samples are not in the concentration range of the prepared standards, additional standards must be prepared to determine detector response.

3.3.7 Desorb the standards in the same manner as the samples following the 16-hour reaction time.

3.4 *Sample preparation:*

3.4.1 Transfer the 150-mg section of the sampling tube to a 2-mL vial. Place the 75-mg section in a separate vial. If the glass wool plugs contain a significant number of adsorbent beads, place them with the appropriate sampling tube section. Discard the glass wool plugs if they do not contain a significant number of adsorbent beads.

3.4.2 Add 1 mL of desorbing solution to each vial.

3.4.3 Seal the vials with Teflon-lined caps and then allow them to desorb for one hour. Shake the vials by hand with vigorous force several times during the desorption time.

3.4.4 Save the used sampling tubes to be cleaned and recycled.

3.5 *Analysis:*

3.5.1 *GC Conditions*

Column Temperature:

Bi-level temperature program—First level: 100 to 140 °C at 4 °C/min following completion of the first level.

Second level: 140 to 180 °C at 20 °C/min following completion of the first level.

Isothermal period: Hold column at 180 °C until the recorder pen returns to baseline (usually about 25 min after injection).

Injector temperature: 180 °C

Helium flow rate: 30 mL/min (detector response will be reduced if nitrogen is substituted for helium carrier gas).

Injection volume: 0.8 µL

GC column: Six-ft x 1/4-in OD (2 mm ID) glass GC column containing 10% UCON 50-HB-5100 + 2% KOH on 80/100 Chromosorb W-AW.

NPD conditions:

Hydrogen flow rate: 3 mL/min

Air flow rate: 50 mL/min

Detector temperature: 275 °C

3.5.2 *Chromatogram:* For an example of a typical chromatogram, see Figure 4.11 in OSHA Method 52.

3.5.3 Use a suitable method, such as electronic integration, to measure detector response.

3.5.4 Use an internal standard method to prepare the calibration curve with several standard solutions of different concentrations. Prepare the calibration curve daily. Program the integrator to report results in µg/mL.

3.5.5 Bracket sample concentrations with standards.

3.6 *Interferences (Analytical)*

3.6.1 Any compound with the same general retention time as the analytes and which also gives a detector response is a potential interference. Possible interferences should be reported to the laboratory with submitted samples by the industrial hygienist.

3.6.2 GC parameters (temperature, column, etc.) may be changed to circumvent interferences.

3.6.3 A useful means of structure designation is GC/MS. It is recommended this procedure be used to confirm samples whenever possible.

3.6.4 The coated adsorbent usually contains a very small amount of residual formaldehyde derivative (Section 4.8).

3.7 *Calculations:*

3.7.1 Results are obtained by use of calibration curves. Calibration curves are prepared by plotting detector response against concentration for each standard. The best line through the data points is determined by curve fitting.

3.7.2 The concentration, in $\mu\text{g/mL}$, for a particular sample is determined by comparing its detector response to the calibration curve. If either of the analytes is found on the backup section, it is added to the amount found on the front section. Blank corrections should be performed before adding the results together.

3.7.3 The acrolein and/or formaldehyde air concentration can be expressed using the following equation:

$$\text{mg}/\text{m}^3 = (\text{A})(\text{B})/\text{C}$$

where A = $\mu\text{g/mL}$ from 3.7.2, B = desorption volume, and C = L of air sampled.

No desorption efficiency corrections are required.

3.7.4 The following equation can be used to convert results in mg/m^3 to ppm.

$$\text{ppm} = (\text{mg}/\text{m}^3)(24.45)/\text{MW}$$

where mg/m^3 = result from 3.7.3, 24.45 = molar volume of an ideal gas at 760 mm Hg and 25 °C, MW = molecular weight (30.0).

4. Backup Data

4.1 Backup data on detection limits, reliable quantitation limits, sensitivity and precision of the analytical method, breakthrough, desorption efficiency, storage, reproducibility, and generation of test atmospheres are available in OSHA Method 52, developed by the Organics Methods Evaluation Branch, OSHA Analytical Laboratory, Salt Lake City, Utah.

4.2 Procedure to Coat XAD-2 Adsorbent with 2-HMP:

4.2.1 Apparatus: Soxhlet extraction apparatus, rotary evaporation apparatus, vacuum dessicator, 1-L vacuum flask, 1-L round-bottomed evaporative flask, 1-L Erlenmeyer flask, 250-mL Buchner funnel with a coarse fritted disc, etc.

4.2.2 Reagents:

4.2.2.1 Methanol, isooctane, and toluene.

4.2.2.2 2-(Hydroxymethyl)piperidine.

4.2.2.3 Amberlite XAD-2 non-ionic polymeric adsorbent, 20 to 60 mesh, Aldrich Chemical XAD-2 was used in this evaluation.

4.2.3 Procedure: Weigh 125 g of crude XAD-2 adsorbent into a 1-L Erlenmeyer flask. Add about 200 mL of water to the flask and then swirl the mixture to wash the adsorbent. Discard any adsorbent that floats to the top of the water and then filter the mixture using a fritted Buchner funnel. Air dry the adsorbent for 2 minutes. Transfer the adsorbent back to the Erlenmeyer flask and then add about 200 mL of methanol to the flask. Swirl and then filter the mixture as before. Transfer the washed adsorbent back to the Erlenmeyer flask and then add about 200 mL of methanol to the flask. Swirl and then filter the

mixture as before. Transfer the washed adsorbent to a 1-L round-bottomed evaporative flask, add 13 g of 2-HMP and then 200 mL of methanol, swirl the mixture and then allow it to stand for one hour. Remove the methanol at about 40 °C and reduced pressure using a rotary evaporation apparatus. Transfer the coated adsorbent to a suitable container and store it in a vacuum desiccator at room temperature overnight. Transfer the coated adsorbent to a Soxhlet extractor and then extract the material with toluene for about 24 hours. Discard the contaminated toluene, add methanol in its place and then continue the Soxhlet extraction for an additional 4 hours. Transfer the adsorbent to a weighted 1-L round-bottom evaporative flask and remove the methanol using the rotary evaporation apparatus. Determine the weight of the adsorbent and then add an amount of 2-HMP, which is 10% by weight of the adsorbent. Add 200 mL of methanol and then swirl the mixture. Allow the mixture to stand for one hour. Remove the methanol by rotary evaporation. Transfer the coated adsorbent to a suitable container and store it in a vacuum desiccator until all traces of solvents are gone. Typically, this will take 2-3 days. The coated adsorbent should be protected from contamination. XAD-2 adsorbent treated in this manner will probably not contain residual acrolein derivative. However, this adsorbent will often contain residual formaldehyde derivative levels of about 0.1 μg per 150 mg of adsorbent. If the blank values for a batch of coated adsorbent are too high, then the batch should be returned to the Soxhlet extractor, extracted with toluene again and then recoated. This process can be repeated until the desired blank levels are attained.

The coated adsorbent is now ready to be packed into sampling tubes. The sampling tubes should be stored in a sealed container to prevent contamination. Sampling tubes should be stored in the dark at room temperature. The sampling tubes should be segregated by coated adsorbent lot number. A sufficient amount of each lot number of coated adsorbent should be retained to prepare analytical standards for use with air samples from that lot number.

4.3 A Procedure to Determine Formaldehyde by Acid Titration: Standardize the 0.1 N HCl solution using sodium carbonate and methyl orange indicator.

Place 50 mL of 0.1 M sodium sulfite and three drops of thymophthalein indicator into a 250-mL Erlenmeyer flask. Titrate the contents of the flask to

a colorless endpoint with 0.1 N HCl (usually one or two drops is sufficient). Transfer 10 mL of the formaldehyde/methanol solution (prepared in 3.3.1) into the same flask and titrate the mixture with 0.1 N HCl, again, to a colorless endpoint. The formaldehyde concentration of the standard may be calculated by the following equation:

$$\text{Formaldehyde, mg/mL} = \frac{\text{acid titer} \times \text{acid normality} \times 30.0}{\text{mL of sample}}$$

This method is based on the quantitative liberation of sodium hydroxide when formaldehyde reacts with sodium sulfite to form the formaldehyde-bisulfite addition product. The volume of sample may be varied depending on the formaldehyde content but the solution to be titrated must contain excess sodium sulfite. Formaldehyde solutions containing substantial amounts of acid or base must be neutralized before analysis.

Appendix C to § 1910.1048—Medical Surveillance—Formaldehyde

I. Health Hazards

The occupational health hazards of formaldehyde are primarily due to its toxic effects after inhalation, after direct contact with the skin or eyes by formaldehyde in liquid or vapor form, and after ingestion.

II. Toxicology

A. Acute Effects of Exposure

1. *Inhalation (breathing):* Formaldehyde is highly irritating to the upper airways. The concentration of formaldehyde that is immediately dangerous to life and health is 100 ppm. Concentrations above 50 ppm can cause severe pulmonary reactions within minutes. These include pulmonary edema, pneumonia, and bronchial irritation which can result in death. Concentrations above 5 ppm readily cause lower airway irritation characterized by cough, chest tightness and wheezing. There is some controversy regarding whether formaldehyde gas is a pulmonary sensitizer which can cause occupational asthma in a previously normal individual. Formaldehyde can produce symptoms of bronchial asthma in humans. The mechanism may be either sensitization of the individual by exposure to formaldehyde or direct irritation by formaldehyde in persons with pre-existing asthma. Upper airway irritation is the most common

respiratory effect reported by workers and can occur over a wide range of concentrations, most frequently above 1 ppm. However, airway irritation has occurred in some workers with exposures to formaldehyde as low as 0.1 ppm. Symptoms of upper airway irritation include dry or sore throat, itching and burning sensations of the nose, and nasal congestion. Tolerance to this level of exposure may develop within 1-2 hours. This tolerance can permit workers remaining in an environment of gradually increasing formaldehyde concentrations to be unaware of their increasingly hazardous exposure.

2. Eye contact: Concentrations of formaldehyde between 0.05 ppm and 0.5 ppm produce a sensation of irritation in the eyes with burning, itching, redness, and tearing. Increased rate of blinking and eye closure generally protects the eye from damage at these low levels, but these protective mechanisms may interfere with some workers' work abilities. Tolerance can occur in workers continuously exposed to concentrations of formaldehyde in this range. Accidental splash injuries of human eyes to aqueous solutions of formaldehyde (formalin) have resulted in a wide range of ocular injuries including corneal opacities and blindness. The severity of the reactions have been directly dependent on the concentration of formaldehyde in solution and the amount of time lapsed before emergency and medical intervention.

3. Skin contact: Exposure to formaldehyde solutions can cause irritation of the skin and allergic contact dermatitis. These skin diseases and disorders can occur at levels well below those encountered by many formaldehyde workers. Symptoms include erythema, edema, and vesiculation or hives. Exposure to liquid formalin or formaldehyde vapor can provoke skin reactions in sensitized individuals even when airborne concentrations of formaldehyde are well below 1 ppm.

4. Ingestion: Ingestion of as little as 30 ml of a 37 percent solution of formaldehyde (formalin) can result in death. Gastrointestinal toxicity after ingestion is most severe in the stomach and results in symptoms which can include nausea, vomiting, and severe abdominal pain. Diverse damage to other organ systems including the liver, kidney, spleen, pancreas, brain, and central nervous systems can occur from the acute response to ingestion of formaldehyde.

B. Chronic Effects of Exposure

Long term exposure to formaldehyde has been shown to be associated with an increased risk of cancer of the nose and accessory sinuses, nasopharyngeal and oropharyngeal cancer, and lung cancer in humans. Animal experiments provide conclusive evidence of a causal relationship between nasal cancer in rats and formaldehyde exposure. Concordant evidence of carcinogenicity includes DNA binding, genotoxicity in short-term tests, and cytotoxic changes in the cells of the target organ suggesting both preneoplastic changes and a dose-rate effect. Formaldehyde is a complete carcinogen and appears to exert an effect on at least two stages of the carcinogenic process.

III. Surveillance considerations

A. History

1. Medical and occupational history: Along with its acute irritative effects, formaldehyde can cause allergic sensitization and cancer. One of the goals of the work history should be to elicit information on any prior or additional exposure to formaldehyde in either the occupational or the non-occupational setting.

2. Respiratory history: As noted above, formaldehyde has recognized properties as an airway irritant and has been reported by some authors as a cause of occupational asthma. In addition, formaldehyde has been associated with cancer of the entire respiratory system of humans. For these reasons, it is appropriate to include a comprehensive review of the respiratory system in the medical history. Components of this history might include questions regarding dyspnea on exertion, shortness of breath, chronic airway complaints, hyperreactive airway disease, rhinitis, bronchitis, bronchiolitis, asthma, emphysema, respiratory allergic reaction, or other preexisting pulmonary disease.

In addition, generalized airway hypersensitivity can result from exposures to a single sensitizing agent. The examiner should, therefore, elicit any prior history of exposure to pulmonary irritants, and any short- or long-term effects of that exposure.

Smoking is known to decrease mucociliary clearance of materials deposited during respiration in the nose and upper airways. This may increase a worker's exposure to inhaled materials such as formaldehyde vapor. In addition, smoking is a potential confounding factor in the investigation of any chronic respiratory disease, including cancer. For these reasons, a

complete smoking history should be obtained.

3. Skin Disorders: Because of the dermal irritant and sensitizing effects of formaldehyde, a history of skin disorders should be obtained. Such a history might include the existence of skin irritation, previously documented skin sensitivity, and other dermatologic disorders. Previous exposure to formaldehyde and other dermal sensitizers should be recorded.

4. History of atopic or allergic diseases: Since formaldehyde can cause allergic sensitization of the skin and airways, it might be useful to identify individuals with prior allergen sensitization. A history of atopic disease and allergies to formaldehyde or any other substances should also be obtained. It is not definitely known at this time whether atopic diseases and allergies to formaldehyde or any other substances should also be obtained. Also it is not definitely known at this time whether atopic individuals have a greater propensity to develop formaldehyde sensitivity than the general population, but identification of these individuals may be useful for ongoing surveillance.

5. Use of disease questionnaires: Comparison of the results from previous years with present results provides the best method for detecting a general deterioration in health when toxic signs and symptoms are measured subjectively. In this way recall bias does not affect the results of the analysis. Consequently, OSHA has determined that the findings of the medical and work histories should be kept in a standardized form for comparison of the year-to-year results.

B. Physical Examination

1. Mucosa of eyes and airways: Because of the irritant effects of formaldehyde, the examining physician should be alert to evidence of this irritation. A speculum examination of the nasal mucosa may be helpful in assessing possible irritation and cytotoxic changes, as may be indirect inspection of the posterior pharynx by mirror.

2. Pulmonary system: A conventional respiratory examination, including inspection of the thorax and auscultation and percussion of the lung fields should be performed as part of the periodic medical examination. Although routine pulmonary function testing is only required by the standard once every year for persons who are exposed over the TWA concentration limit, these tests have an obvious value in investigating possible respiratory

dysfunction and should be used wherever deemed appropriate by the physician. In cases of alleged formaldehyde-induced airway disease, other possible causes of pulmonary disfunction (including exposures to other substances) should be ruled out. A chest radiograph may be useful in these circumstances. In cases of suspected airway hypersensitivity or allergy, it may be appropriate to use bronchial challenge testing with formaldehyde or methacholine to determine the nature of the disorder. Such testing should be performed by or under the supervision of a physician experienced in the procedures involved.

3. *Skin*: The physician should be alert to evidence of dermal irritation of sensitization, including reddening and inflammation, urticaria, blistering, scaling, formation of skin fissures, or other symptoms. Since the integrity of the skin barrier is compromised by other dermal diseases, the presence of such disease should be noted. Skin sensitivity testing carries with it some risk of inducing sensitivity, and therefore, skin testing for formaldehyde sensitivity should not be used as a routine screening test. Sensitivity testing may be indicated in the investigation of a suspected existing sensitivity. Guidelines for such testing have been prepared by the North American Contact Dermatitis Group.

C. Additional Examinations or Tests

The physician may deem it necessary to perform other medical examinations or tests as indicated. The standard provides a mechanism whereby these additional investigations are covered under the standard for occupational exposure to formaldehyde.

D. Emergencies

The examination of workers exposed in an emergency should be directed at the organ systems most likely to be affected. Much of the content of the examination will be similar to the periodic examination unless the patient has received a severe acute exposure requiring immediate attention to prevent serious consequences. If a severe overexposure requiring medical intervention or hospitalization has occurred, the physician must be alert to the possibility of delayed symptoms. Followup nonroutine examinations may be necessary to assure the patient's well-being.

E. Employer Obligations

The employer is required to provide the physician with the following information: A copy of this standard and appendices A, C, D, and E; a description

of the affected employee's duties as they relate to his or her exposure concentration; an estimate of the employee's exposure including duration (e.g. 15 hr/wk, three 8-hour shifts, full-time); a description of any personal protective equipment, including respirators, used by the employee; and the results of any previous medical determinations for the affected employee related to formaldehyde exposure to the extent that this information is within the employer's control.

F. Physician's Obligations

The standard requires the employer to obtain a written statement from the physician. This statement must contain the physician's opinion as to whether the employee has any medical condition which would place him or her at increased risk of impaired health from exposure to formaldehyde or use of respirators, as appropriate. The physician must also state his opinion regarding any restrictions that should be placed on the employee's exposure to formaldehyde or upon the use of protective clothing or equipment such as respirators. If the employee wears a respirator as a result of his or her exposure to formaldehyde, the physician's opinion must also contain a statement regarding the suitability of the employee to wear the type of respirator assigned. Finally, the physician must inform the employer that the employee has been told the results of the medical examination and of any medical conditions which require further explanation or treatment. This written opinion is not to contain any information on specific findings or diagnoses unrelated to occupational exposure to formaldehyde.

The purpose in requiring the examining physician to supply the employer with a written opinion is to provide the employer with a medical basis to assist the employer in placing employees initially, in assuring that their health is not being impaired by formaldehyde, and to assess the employee's ability to use any required protective equipment.

Appendix D to § 1910.1048— Nonmandatory Medical Disease Questionnaire

A. Identification

Plant Name _____
Date _____
Employee Name _____
S.S. # _____
Job Title _____
Birthdate: _____
Age: _____

Sex: _____
Height: _____
Weight: _____

B. Medical History

1. Have you ever been in the hospital as a patient?
Yes ☐ No ☐
If yes, what kind of problem were you having? _____
2. Have you ever had any kind of operation?
Yes ☐ No ☐
If yes, what kind? _____
3. Do you take any kind of medicine regularly?
Yes ☐ No ☐
If yes, what kind? _____
4. Are you allergic to any drugs, foods, or chemicals?
Yes ☐ No ☐
If yes, what kind of allergy is it? _____
What causes the allergy? _____
5. Have you ever been told that you have asthma, hayfever, or sinusitis?
Yes ☐ No ☐
6. Have you ever been told that you have emphysema, bronchitis, or any other respiratory problems?
Yes ☐ No ☐
7. Have you ever been told you had hepatitis?
Yes ☐ No ☐
8. Have you ever been told that you had cirrhosis?
Yes ☐ No ☐
9. Have you ever been told that you had cancer?
Yes ☐ No ☐
10. Have you ever had arthritis or joint pain?
Yes ☐ No ☐
11. Have you ever been told that you had high blood pressure?
Yes ☐ No ☐
12. Have you ever had a heart attack or heart trouble?
Yes ☐ No ☐

B-1. Medical History Update

1. Have you been in the hospital as a patient any time within the past year?
Yes ☐ No ☐
If so, for what condition? _____
2. Have you been under the care of a physician during the past year?
Yes ☐ No ☐
If so, for what condition? _____
3. Is there any change in your breathing since last year?
Yes ☐ No ☐
Better? _____

Worse? _____
 No change? _____
 If change, do you know why? _____

4. Is your general health different this year from last year?
 Yes ☐ No ☐
 If different, in what way? _____

5. Have you in the past year or are you now taking any medication on a regular basis?
 Yes ☐ No ☐
 Name Rx _____
 Condition being treated _____

C. Occupational History

1. How long have you worked for your present employer?

2. What jobs have you held with this employer? Include job title and length of time in each job.

3. In each of these jobs, how many hours a day were you exposed to chemicals?

4. What chemicals have you worked with most of the time?

5. Have you ever noticed any type of skin rash you feel was related to your work?
 Yes ☐ No ☐

6. Have you ever noticed that any kind of chemical makes you cough?
 Yes ☐ No ☐

Wheeze?
 Yes ☐ No ☐
 Become short of breath or cause your chest to become tight?
 Yes ☐ No ☐

7. Are you exposed to any dust or chemicals at home?
 Yes ☐ No ☐

If yes, explain: _____

8. In other jobs, have you ever had exposure to:

Wood dust?
 Yes ☐ No ☐
 Nickel of chromium?
 Yes ☐ No ☐
 Silica (foundry, sand blasting)?
 Yes ☐ No ☐
 Arsenic or asbestos?
 Yes ☐ No ☐
 Organic solvents?
 Yes ☐ No ☐
 Urethane foams?
 Yes ☐ No ☐

C-1. Occupational History Update

1. Are you working on the same job this year as you were last year?
 Yes ☐ No ☐

If not, how has your job changed? _____

2. What chemicals are you exposed to on your job?

3. How many hours a day are you exposed to chemicals?

4. Have you noticed any skin rash within the past year you feel was related to your work?
 Yes ☐ No ☐

If so, explain circumstances: _____

5. Have you noticed that any chemical makes you cough, be short of breath, or wheeze?
 Yes ☐ No ☐

If so, can you identify it? _____

D. Miscellaneous

1. Do you smoke?
 Yes ☐ No ☐

If so, how much and for how long? _____

Pipe _____
 Cigars _____
 Cigarettes _____

2. Do you drink alcohol in any form?
 Yes ☐ No ☐

If so, how much, how long, and how often? _____

3. Do you wear glasses or contact lenses?
 Yes ☐ No ☐

4. Do you get any physical exercise other than that required to do your job?
 Yes ☐ No ☐

If so, explain: _____

5. Do you have any hobbies or "side jobs" that require you to use chemicals, such as furniture stripping, sand blasting, insulation or manufacture of urethane foam, furniture, etc?
 Yes ☐ No ☐

If so, please describe, giving type of business or hobby, chemicals used and length of exposures.

E. Symptoms Questionnaire

1. Do you ever have any shortness of breath?
 Yes ☐ No ☐

If yes, do you have to rest after climbing several flights of stairs?
 Yes ☐ No ☐

If yes, if you walk on the level with people your own age, do you walk slower than they do?
 Yes ☐ No ☐

If yes, if you walk slower than a normal pace, do you have to limit the distance that you walk?
 Yes ☐ No ☐

If yes, do you have to stop and rest while bathing or dressing?
 Yes ☐ No ☐

2. Do you cough as much as three months out of the year?
 Yes ☐ No ☐

If yes, have you had this cough for more than two years?
 Yes ☐ No ☐

If yes, do you ever cough anything up from chest?
 Yes ☐ No ☐

3. Do you ever have a feeling of smothering, unable to take a deep breath, or tightness in your chest?
 Yes ☐ No ☐

If yes, do you notice that this on any particular day of the week?
 Yes ☐ No ☐

If yes, what day or the week?
 Yes ☐ No ☐

If yes, do you notice that this occurs at any particular place?
 Yes ☐ No ☐

If yes, do you notice that this is worse after you have returned to work after being off for several days?
 Yes ☐ No ☐

4. Have you ever noticed any wheezing in your chest?
 Yes ☐ No ☐

If yes, is this only with colds or other infections?
 Yes ☐ No ☐

Is this caused by exposure to any kind of dust or other material?
 Yes ☐ No ☐

If yes, what kind? _____

5. Have you noticed any burning, tearing, or redness of your eyes when you are at work?
 Yes ☐ No ☐

If so, explain circumstances: _____

6. Have you noticed any sore or burning throat or itchy or burning nose when you are at work?
 Yes ☐ No ☐

If so, explain circumstances: _____

7. Have you noticed any stuffiness or dryness of your nose?
 Yes ☐ No ☐

8. Do you ever have swelling of the eyelids or face?
 Yes ☐ No ☐

9. Have you ever been jaundiced?
 Yes ☐ No ☐

If yes, was this accompanied by any pain?
 Yes ☐ No ☐

10. Have you ever had a tendency to bruise easily or bleed excessively?
 Yes ☐ No ☐

11. Do you have frequent headaches that are not relieved by aspirin or tylenol?
 Yes ☐ No ☐

If yes, do they occur at any particular time of the day or week?
 Yes ☐ No ☐

If yes, when do they occur? _____

12. Do you have frequent episodes of nervousness or irritability?

- Yes ☐ No ☐
13. Do you tend to have trouble concentrating or remembering?
Yes ☐ No ☐
14. Do you ever feel dizzy, light-headed, excessively drowsy or like you have been drugged?
Yes ☐ No ☐
15. Does your vision ever become blurred?
Yes ☐ No ☐
16. Do you have numbness or tingling of the hands or feet or other parts of your body?
Yes ☐ No ☐
17. Have you ever had chronic weakness or fatigue?
Yes ☐ No ☐
18. Have you ever had any swelling of your feet or ankles to the point where you could not wear your shoes?
Yes ☐ No ☐
19. Are you bothered by heartburn or indigestion?
Yes ☐ No ☐
20. Do you ever have itching, dryness, or peeling and scaling of the hands?
Yes ☐ No ☐
21. Do you ever have a burning sensation in the hands, or reddening of the skin?
Yes ☐ No ☐
22. Do you ever have cracking or bleeding of the skin on your hands?
Yes ☐ No ☐
23. Are you under a physician's care?
Yes ☐ No ☐
If yes, for what are you being treated? _____
24. Do you have any physical complaints today?
Yes ☐ No ☐
If yes, explain? _____
25. Do you have other health conditions not covered by these questions?
Yes ☐ No ☐
If yes, explain: _____

Appendix E to § 1910.1048—Qualitative and Quantitative Fit Testing Procedures

I. FIT Test Protocols

Because exposure to formaldehyde can affect the employee's ability to detect common odorants, fit test results from the isoamyl acetate test must be augmented by results from either the saccharin or irritant smoke test.

A. The employer shall include the following provisions in the fit test procedures. These provisions apply to both qualitative fit testing (QLFT) and quantitative fit testing (QNFT).

1. The test subject shall be allowed to pick the most comfortable respirator from a selection including respirators of various sizes from different

manufacturers. The selection shall include at least three sizes of elastomeric facepieces of the type of respirator that is to be tested, i.e., three sizes of half mask; or three sizes of full facepiece; and units from at least two manufacturers.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine a comfortable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning the respirator. This instruction may not constitute the subject's formal training on respirator use, as it is only a review.

3. The test subject shall be informed that he/she is being asked to select the respirator which provides the most comfortable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each facepiece up to the face and eliminate those which obviously do not give a comfortable fit.

5. The more comfortable facepieces are noted; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in item 6 below. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include reviewing the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:

- (a) position of the mask on the nose.
- (b) room for eye protection.
- (c) room to talk.
- (d) position of mask on face and cheeks.

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

- (a) chin properly placed;
- (b) adequate strap tension, not overly tightened;
- (c) fit across nose bridge;
- (d) respirator of proper size to span distance from nose to chin;
- (e) tendency of respirator to slip;
- (f) self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct the negative and positive pressure fit checks as described below or ANSI Z88.2-1980. Before conducting the negative or positive pressure test, the subject shall be told to seat the mask on the face by

moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the fit check tests.

(a) *Positive pressure test.* Close off the exhalation valve and exhale gently onto the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.

(b) *Negative pressure test.* Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the facepiece collapses slightly, and hold the breath for ten seconds. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, or long sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician trained in respiratory disease or pulmonary medicine to determine whether the test subject can wear a respirator while performing her or his duties.

11. The test subject shall be given the opportunity to wear the successfully fitted respirator for a period of two weeks. If at any time during this period the respirator becomes uncomfortable, the test subject shall be given the opportunity to select a different facepiece and to be retested.

12. The employer shall certify that a successful fit test has been administered to the employee. The certification shall include the following information:

- (a) Name of employee;
- (b) Type, brand and size of respirator; and
- (c) Date of test;

Where QNFT is used, the fit factor, strip chart, or other recording of the results of the test, shall be retained with the certification. The certification shall be maintained until the next fit test is administered.

13. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure.

The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

14. Test Exercises. The test subject shall perform exercises, in the test environment, in the manner described below:

(a) *Normal breathing.* In a normal standing position, without talking, the subject shall breathe normally.

(b) *Deep breathing.* In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as to not hyperventilate.

(c) *Turning head side to side.* Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(d) *Moving head up and down.* Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(e) *Talking.* The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

(f) *Grimace.* The test subject shall grimace by smiling or frowning.

(g) *Bending over.* The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units which prohibit bending at the waist.

(h) *Normal breathing.* Same as exercise 1.

Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds.

The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become uncomfortable, another model of respirator shall be tried.

B. Qualitative Fit Test (QLFT) Protocols

1. *General.* (a) The employer shall assign specific individuals who shall assume full responsibility for

implementing the respirator qualitative fit test program.

(b) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and assure that these equipment is in proper working order.

(c) The employer shall assure the QLFT equipment is kept clean and well maintained so as to operate at the parameters for which it was designed.

2. *Isoamyl Acetate Protocol*—(a) *Odor threshold screening.* The odor threshold screening test, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate.

(1) Three 1-liter glass jars with metal lids are required.

(2) Odor free water (e.g., distilled or spring water) at approximately 25 degrees C shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known as isopentyl acetate) stock solution is prepared by adding 1 cc of pure IAA to 800 cc of odor free water in a 1 liter jar and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well ventilated but shall not be connected to the same recirculating ventilation system.

(5) The odor test solution is prepared in a second jar by placing 0.4 cc of the stock solution into 500 cc of odor free water using a clear dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor free water.

(7) The odor test and test blank jars shall be labeled 1 and 2 for jar identification. Labels shall be placed on the lids so they can be periodically peeled, dried off and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two jars (i.e., 1 and 2): "The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contain a small amount of banana oil. Be sure the covered are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of

the bottle. Indicate to the test conductor which bottle contains banana oil."

(9) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) *Isoamyl acetate fit test.* (1) The fit test chamber shall be similar to a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors. The cartridges or masks shall be changed at least weekly.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 cc of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the head exercises; or to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana like odor of IAA, the test has failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the test has failed, the subject shall return to the selection room and remove the respirator, repeat the odor sensitivity test, select and put on

another respirator, return to the test chamber and again begin the procedure described in (1) through (7) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait about 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) When a respirator is found that passes the test, its efficiency shall be demonstrated for the subject by having the subject break the face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test. To keep the test area from becoming contaminated, the used towels shall be kept in a self sealing bag so there is no significant IAA concentration build-up in the test chamber during subsequent tests.

3. Saccharin Solution Aerosol Protocol. The saccharin solution aerosol QLFT protocol is the only currently available, validated test protocol for use with particulate disposable dust respirators not equipped with high-efficiency filters. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) *Taste threshold screening.* The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) Threshold screening as well as fit testing subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a ¾-inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her wide open mouth with tongue extended.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer the test conductor shall spray the *threshold check solution* into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The *threshold check solution* consists of 0.83 grams of sodium saccharin USP in 1 cc of warm water. It

can be prepared by putting 1 cc of the fit test solution (see (b)(5) below) in 100 cc of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject may not perform the saccharin fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 cc of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) *Saccharin solution aerosol fit test procedure.* (1) The test subject may not eat, drink (except plain water), or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section (a) above. The respirator shall be properly adjusted and equipped with a particular filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 cc of warm water.

(6) As before, the test subject shall breathe through the open mouth with tongue extended.

(7) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test.

(8) After generating the aerosol the test subject shall be instructed to perform the exercises in section I. A. 14 above.

(9) Every 30 seconds the aerosol concentration shall be replenished using

one half the number of squeezes as initially.

(10) The test subject shall indicate to the test conductor if any time during the fit test the taste of saccharin is detected.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and a different respirator shall be tried.

4. Irritant Fume Protocol. (a) The respirator to be tested shall be equipped with high-efficiency particulate air (HEPA) filters.

(b) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its characteristic odor.

(c) Break both ends of a ventilation smoke tube containing stannic oxychloride, such as the MSA part No. 5645, or equivalent. Attach one end of the smoke tube to a low flow air pump set to deliver 200 milliliters per minute.

(d) If a half-mask is being fitted, advise the test subject that the smoke can be irritating to the eyes and instruct the subject to keep his/her eyes closed while the test is performed.

(e) The test conductor shall direct the stream of irritant smoke from the smoke tube towards the face seal area of the test subject. He/She shall begin at least 12 inches from the facepiece and gradually move to within one inch, moving around the whole perimeter of the mask.

(f) The exercises identified in section I. A. 14 above shall be performed by the test subject while the respirator seal is being challenged by the smoke.

(g) Each test subject passing the smoke test without evidence of a response shall be given a sensitivity check of the smoke from the same tube once the respirator has been removed to determine whether he/she reacts to the smoke. Failure to evoke a response shall void the fit test.

(h) The fit test shall be performed in a location with exhaust ventilation sufficient to prevent general contamination of the testing area by the test agent.

C. Quantitative Fit Test (QNFT) Protocol

1. General. (a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator quantitative fit test program.

(b) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and assure that test equipment is in proper working order.

(c) The employer shall assure that QNFT equipment is kept clean and well maintained so as to operate at the parameters for which it was designed.

2. *Definitions.* (a) Quantitative fit test. The test is performed in a test chamber. The normal air-purifying element of the respirator is replaced by a high-efficiency particulate air (HEPA) filter in the case of particulate QNFT aerosols or a sorbent offering contaminant penetration protection equivalent to high-efficiency filters where the QNFT test agency is a gas or vapor.

(b) Challenge agent means the aerosol, gas or vapor introduced into a test chamber so that its concentration inside and outside the respirator may be measured.

(c) Test subject means the person wearing the respirator for quantitative fit testing.

(d) Normal standing position means standing erect and straight with arms down along the sides and looking straight ahead.

(e) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(f) Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers which calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method.

(g) "Fit Factor" means the ratio of challenge agent concentration outside with respect to the inside of a respirator inlet covering (facepiece or enclosure).

3. *Apparatus.* (a) Instrumentation. Aerosol generation, dilution, and measurement systems using corn oil or sodium chloride as test aerosols shall be used for quantitative fit testing.

(b) Test chamber. The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the challenge agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the challenge agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(c) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high-efficiency particulate filter supplied by the same manufacturer.

(d) The sampling instrument shall be selected so that a strip chart record may be made of the test showing the rise and fall of the challenge agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers which integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

(e) The combination of substitute air-purifying elements, challenge agent and challenge agent concentration in the test chamber shall be such that the test subject is not exposed in excess of an established exposure limit for the challenge agent at any time during the testing process.

(f) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g., where the respirator is probed), a free air flow is allowed into the sampling line at all times and so that there is no interference with the fit or performance of the respirator.

(g) The test chamber and test set up shall permit the person administering the test to observe the test subject inside the chamber during the test.

(h) The equipment generating the challenge atmosphere shall maintain the concentration of challenge agent inside the test chamber constant to within a 10 percent variation for the duration of the test.

(i) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event inside the test chamber and its being recorded.

(j) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and of the same material. The length of the two lines shall be equal.

(k) The exhaust flow from the test chamber shall pass through a high-efficiency filter before release.

(l) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(m) The limitations of instrument detection shall be taken into account when determining the fit factor.

(n) Test respirators shall be maintained in proper working order and

inspected for deficiencies such as cracks, missing valves and gaskets, etc.

4. *Procedural Requirements.* (a) When performing the initial positive or negative pressure test the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these tests.

(b) An abbreviated screening isoamyl acetate test or irritant fume test may be utilized in order to quickly identify poor fitting respirators which passed the positive and/or negative pressure test and thus reduce the amount of QNFT time. When performing a screening isoamyl acetate test, combination high-efficiency organic vapor cartridges/canisters shall be used.

(c) A reasonably stable challenge agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain type of test units the determination of the challenge agent stability may be established after the test subject has entered the test environment.

(d) Immediately after the subject enters the test chamber, the challenge agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(e) A stable challenge concentration shall be obtained prior to the actual start of testing.

(f) Respirator restraining straps shall not be overtightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonable comfortable fit typical of normal use.

(g) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested. If two of the three required tests are terminated, the fit shall be deemed inadequate.

(h) In order to successfully complete a QNFT, three successful fit tests are required. The results of each of the three independent fit tests must exceed the minimum fit factor needed for the class of respirator (e.g., half mask respirator, full facepiece respirator).

(i) Calculation of fit factors.

(1) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration inside the respirator.

(2) The average test chamber concentration is the arithmetic average of the test chamber concentration at the beginning and of the end of the test.

(3) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

- (i) Average peak concentration
- (ii) Maximum peak concentration
- (iii) Integration by calculation of the area under the individual peak for each exercise. This includes computerized integration.

(j) Interpretation of test results. The fit factor established by the quantitative fit testing shall be the lowest of the three fit factor values calculated from the three required fit tests.

(k) The test subject shall not be permitted to wear a half mask, or full facepiece respirator unless a minimum fit factor equivalent to at least 10 times the hazardous exposure level is obtained.

(l) Filters used for quantitative fit testing shall be replaced at least weekly, or whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media. Organic vapor cartridges/canisters shall be replaced daily (when used) or sooner if there is any indication of breakthrough by a test agent.

PART 1926—[AMENDED]

Subpart D—[Amended]

6. The authority citation for Subpart D of Part 1926 continues to read as follows:

Authority: Secs. 4, 6, 8 Occupational Safety and Health Act of 1970, 29 U.S.C. 653, 655, 657; sec. 107, Contract Work Hours and Safety Standards Act (Construction Safety

Act), 40 U.S.C. 333, and Secretary of Labor's Orders 12-71 (36 FR 8754), 8-76 (41 FR 25059), or 9-83 (48 FR 35736), as applicable. Sections 1926.55(c) and 1926.58 also issued under 29 CFR Part 1911.

7. A new paragraph (d) is added to § 1926.55 to read as follows:

§ 1926.55 Gases, vapors, fumes, dusts and mists.

* * * * *

(d) Paragraphs (a) and (b) of this section do not apply to the exposure of employees to formaldehyde. Whenever any employee is exposed to formaldehyde, the requirements of § 1910.1048 of this title shall apply.

[FR Doc. 87-27329 Filed 12-2-87; 12:00 pm]

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Friday
December 4, 1987

Part III

**Federal Retirement
Thrift Investment
Board**

5 CFR Part 1605
Error Correction Regulations; Final Rule

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

5 CFR Part 1605

Error Correction Regulations

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Final rule.

SUMMARY: The Federal Retirement Thrift Investment Board (Board) is issuing final regulations governing the correction of errors which may have occurred during the course of administering the Thrift Savings Plan. These regulations reflect interim regulations on error correction issued by the Board on May 13, 1987 (52 FR 17919) and July 22, 1987 (52 FR 27527). The final rule adopts these interim rules, with amendments.

These regulations relate to errors that may have been committed by agencies or the Board during the course of processing data on employee participation in the Thrift Savings Plan. These errors may occur as a consequence of action, or lack of action, on the part of an employee's agency or on the part of the Board. In addition, these regulations specify the action to be taken where an employee fails to participate, or is delayed in participating, in the Thrift Savings Plan for reasons beyond his or her control and where there has not been an error on the part of the agency. Finally, these regulations address adjustment to Thrift Savings Plan contributions which must be made when there has been a retroactive adjustment to an employee's pay.

EFFECTIVE DATE: Final rules effective December 4, 1987.

FOR FURTHER INFORMATION CONTACT: John J. O'Meara, (202) 653-2573, Federal Retirement Thrift Investment Board, P.O. Box 18899, Washington, DC 20036.

SUPPLEMENTARY INFORMATION:

I. Background

The Thrift Savings Plan is administered by the Board. However, employees do not, for the purpose of making contributions, deal directly with the Board. Rather, they submit election forms to their agency and that agency executes these forms by deducting the contribution from their pay and forwarding that contribution, along with any applicable government contribution, to the Board's recordkeeper. Since November 1986, the Board's recordkeeping function has been performed by the National Finance Center, Department of Agriculture, New Orleans, Louisiana, which is under contract to the Board. The National

Finance Center posts contributions and earnings to an employee's account. The Board is responsible for establishing procedures and policies for the Thrift Savings Plan. The potential for error occurs throughout this system and the interim error correction regulations identified the types of errors which may occur and the procedures that should be used to make corrections.

Ten federal agencies, two employee unions, and two federal employees commented on the interim regulations. In addition to considering these comments, the Board has consulted with other federal regulators and some federal payroll and personnel officers who provided informal suggestions on improving these procedures. Comments on the interim regulations concentrated mainly on the subjects of fairness and operational efficiency.

II. Section-by-Section Analysis of the Regulations

A. Section 1605.1 Definitions

Two comments were received on this section proposing clarification to existing definitions. The definition of "agency" has been changed to make clear that, where there is a division of responsibility, that term applies to both the organization which took the action affecting the employee's Thrift Savings Plan participation and the organization which is responsible for taking corrective action. The definition of the term "Recordkeeper" has been changed to show that the Recordkeeper is under contract to the Board. One commentator suggested that term "Days" be added to the list of terms and that it be defined to mean work days. The final regulation includes the term "Days", but, it has been defined to mean calendar days. This is consistent with the meaning which the Board had attached to that term as it appeared in the interim regulations and there were no persuasive reasons given for lengthening all of the time periods within which action must be taken under these rules.

B. Section 1605.2 Failure To Participate or Delay in Participation

Twelve comments were received on this section.

1. Paragraph (b)(1). This paragraph was changed by adding a new sentence stating that no retroactive contributions would be permitted in cases where the agency did not cause the employee's failure to participate or delay in participation. This concept was implicit in the interim regulation because there was no provision authorizing retroactive payments for those situations.

2. Subparagraph (b)(2)(i). This subparagraph has been revised to require agencies to correct an employee's personnel records as well as payroll records. This action is necessary because personnel records provide the permanent record of an employee's Thrift Savings Plan participation.

3. Subparagraph (b)(2)(ii). This subparagraph was changed by adding the requirement that the employee must make his or her election to have the error corrected within 30 days of receiving a notification of the error by the agency or forfeit the opportunity to do so. This requirement is necessary in order to avoid situations where agencies are stymied for taking corrective action or clearing their records by an employee's refusal to decide what to do within a reasonable period of time. This subparagraph was also changed by adding five new sentences at the end. The first three of these sentences suspend an employee's retroactive payment schedule whenever the employee has insufficient net pay to make the contributions or where the annual ceiling on tax-deferred contributions relating to a prior year has been reached. Absent this instruction, an employee on leave without pay or one who has reached the annual ceiling for contributions could not receive the full benefit of this correction procedure. The fourth sentence also provides that pay periods occurring during the period of suspended payments will not count against the maximum number of pay periods within which the employee may correct the error. The final sentence makes clear that employees do not have the option of making a payment which is less than what he or she agreed to on the equal payment schedule. The maximum number of pay periods permitted under the regulations for retroactive contributions provide a sufficient period of time over which an employee can reasonably be expected to catch up on his or her contributions. Partial or unequal payments would create unnecessary operational difficulties for agencies processing these contributions.

4. Subparagraph (b)(2)(iii). In the interim regulations, this subparagraph stated that an employee could only terminate the payment schedule in situations where the employee separated from government service. One agency commented that this provision was too restrictive. The final regulations now provide that an employee may stop making the retroactive contributions; however, this decision will be irrevocable. This subparagraph was also clarified with respect to the employee's

option to accelerate the retroactive contribution on separation from government service by making a lump sum contribution from his or her final salary payment. Questions were asked whether the lump sum annual leave payment could also be a source of funds from which the final contribution could be paid. Because the annual leave payment does not qualify as "pay" for purposes of employee contributions, the final regulation excludes this source of funds for purposes of an employee's final accelerated contribution.

5. Subparagraph (b)(2)(iv). The Board received three comments which pointed out that it was not clear in the interim regulations how the government matching contributions will correlate with the retroactive employee contributions. The revised subparagraph provides that the matching contribution will be paid by the agency in equal installments over the employee's equal payment contribution schedule. The Board also received a suggestion that the agency should contribute the entire matching amount as soon as it detects the error. This suggestion was rejected because the government match under the statute is only contributed as a consequence of an employee making an identical contribution. A lump sum government match in advance of an employee completing a payment schedule could also create overpayment collection problems whenever an employee decided not to make contributions, decided not to make up the entire amount, or decided to terminate the payment schedule before it was completed.

6. Subparagraph (b)(2)(v). Two comments were received on subparagraph (b)(2)(v). One suggested that the one percent basic contribution should be paid during the pay period following the agency determination that there was an error, not during the first period of the payment schedule. The Board decided to change this regulation to permit an agency payment of the government basic contribution in advance of the first payment of the payment schedule, but no later than 30 days after the agency determined that an error had occurred. The second comment recommended that the regulations define the salary base that will be used to compute the government basic contribution and make specific reference to the number of pay periods on which the basic government contribution will be based. No changes were made in response to this comment because the salary base used for computing the government basic is the same as the salary base used for other

Thrift Savings Plan calculations and the number of applicable pay periods is defined by the period over which the error occurred.

7. Subparagraph (b)(2)(vi). Three comments were received on subparagraph (b)(2)(vi), all suggesting that employees should receive retroactive interest where the agency erroneously delayed an employee's participation in the Plan. The Board does not have authority to use the account balances of other Plan participants for this purpose. In addition, the Board does not believe that it has the authority to direct an agency to pay penalty interest out of its appropriated funds, since those funds may or may not be legally available for that type of expenditure. At the same time, the Board decided that this provision, prohibiting the payment of retroactive interest into an employee's account from any source, was too restrictive. For that reason, the final regulation (which is now designated (b)(2)(vii)) has been changed to prohibit the Board from depositing retroactive interest in an employee's account as a consequence of agency error. However an agency, under the revised provision, is free to make this type of deposit if it has determined that it has the authority to spend its funds for this purpose.

8. Subparagraph (b)(2)(viii). The Board decided to add a new paragraph (b)(2)(viii) to this section. The new paragraph states that retroactive payments are not subject to the maximum limitations on contributions per pay period. At the same time, these payments will count against the annual ceilings on tax-deferred contributions. This instruction was necessary because the law does not require retroactive payments to be included in calculations of pay period limitations on current contributions.

9. Subparagraph (b)(2)(ix). A new provision was added to the final regulations which establishes the order of precedence when, because of insufficient net pay, the agency must choose between deducting the employee's regular Thrift Savings Plan contribution and deducting the employee's make-up contribution. In this situation, the employee's regular contribution will take precedence over his or her make-up contribution.

C. Section 1605.3 Insufficient deduction or contribution.

The correction procedure for an agency error under § 1605.3 is essentially the same as the procedure for correcting an error under § 1605.2. For this reason, all of the changes made to subsection (b) of § 1605.2 were also

made to subsection (b) of § 1605.3. In addition to these changes, the Board decided to add a new paragraph (b)(9) to section 1605.3 to address the proration of employee and government retroactive contributions to the investment funds. If an employee has a current election form, these contributions will be deposited in the investment fund or funds designated on that form. Employees who do not have a current election form will be given an opportunity to submit one solely for the purpose of designating which fund or funds will receive the contributions. In those situations where there is no current election form and the employee decides not to submit one, all of the retroactive contributions will be invested in the Government Securities Investment Fund.

D. Section 1605.4 Excess deduction or contribution.

1. Subsection (a). This subsection was revised to make clear that an error of excess contribution or overdeduction may occur even though an agency accurately executes the employee's election. This is because the error may consist of a salary overpayment which will automatically trigger an excess deduction and government contribution if the employee had elected to make a percent of pay deduction. For this reason, salary overpayment was identified as an error requiring correction in paragraph (a).

2. Subsection (b). Two agencies recommended that the time period for making a correction under this section be extended. The interim regulation provided in subsection (b) that the corrective actions must take place no later than the pay period following the agency's discovery of the error. As revised, the agencies have 30 days from the date of discovering the error to complete the corrective action.

3. Paragraph (b)(1). This paragraph was changed to require agencies to correct personnel records as well as payroll records. In addition, a new sentence was added to instruct agencies to query the Recordkeeper whenever the adjustment involves the Common Stock Index Investment Fund or the Fixed Income Investment Fund in order to determine whether there is an investment loss attributable to the excess contribution and to identify the appropriate investment funds which should be adjusted to correct this error. This procedure is necessary in order for the agency to correct certain types of errors involving investment loss and to deal with situations where employees

transfer contributions among investment funds.

4. Paragraph (b) (2) and (3). Paragraph (2) was changed to instruct the agency to recover, minus any investment loss, the amount of the excess employee and government contribution. Paragraph (b)(3) was revised to require the agency to return the full amount of the overdeducted employee contribution to the employee and to credit its account with the excess government contribution, minus any investment loss. This means that whenever there has been an investment loss on excess contributions because of agency error, the agency will absorb that loss.

5. Paragraph (b)(4). Four comments were received on this paragraph. The interim regulation provided that the earnings on excess employee and government contributions would remain in the employee's account unless the account was liquidated because of the correction. One comment proposed that the earnings on the government excess contribution be returned to the agency rather than remain in the employee's account. The Board's treatment of these earnings is consistent with IRS Revenue Ruling 77-200 which provides that erroneous employer contributions may be returned to the employer within one year of the mistake, but that earnings on these contributions may not be returned. Another comment suggested that the regulations were inconsistent because paragraph (b)(4) allows an employee to keep earnings on excess contributions, while §§ 1605.2 and 1605.3 do not provide that the Board will pay earnings on underdeductions or where there is a failure to deduct. The reason why there is a difference between these regulations is that paragraph (b)(4) is dealing with a situation where there are earnings for the Board to credit to an employee's account and, in the other situations, the Plan has no earnings to credit to the employee's account. Finally, an agency noted that the Board's regulation does not provide notice of the corrections being made to the employee. This is because employees will be routinely advised of these corrections in the participant account statement.

6. Paragraph (b)(5). The language in this paragraph was deleted as unnecessary in light of the changes which had been made to paragraphs (b) (2) and (3). Paragraph (b)(6) of the interim regulations was redesignated paragraph (b)(5).

7. Paragraph (b)(6). A new paragraph (b)(6) was added to this section in order to authorize an employee to file a claim with his or her agency whenever the agency fails to comply with paragraph

(b)(3) and return to the employee the full amount of the erroneous contribution undiminished by any investment loss attributable to agency error.

E. Section 1605.5 Delayed or Erroneous Posting of Contributions or Earnings

Two comments were received on this section. The first comment recommended that the regulation state that the errors of the Recordkeeper are Board errors. The final regulation provides that corrective action will be taken if the Board or the Recordkeeper fails to post accurately contributions or earnings to an employee's account. The second comment proposed that the correction take place within seven calendar days of its discovery. At this time, the Board is unwilling to designate a time period for correction because information needed to make the correction may not be readily available to the Board. This paragraph was changed by adding a final sentence which states that it does not apply to delayed postings which are due to erroneous agency data input or delay in the delivery of data to the Recordkeeper.

F. Section 1605.6 Agency Allocation to Incorrect Account

1. Subsection (b). One comment suggested that the time period for making this correction be extended. Under the interim regulation, the agency had to correct the error no later than the pay period following the agency's discovery of the error. The final regulation has been changed to require that the error be corrected no later than 30 days following the agency's discovery of the error.

2. Paragraph (b)(1). Two comments suggested that the regulation should be changed to require notice of the correction to the employee. No change was made to this paragraph because employees will receive notice of this correction in the participant's account statement.

3. Paragraph (b)(5). The Board decided to delete paragraph (b)(5) of the interim regulation because it covered a requirement on correction of records that is also addressed by paragraph (b)(1). In its place, there is new language requiring an agency to accept a claim for compensation whenever an employee alleges that contributions were incorrectly allocated to the wrong account and because of this the employee suffered an investment loss that otherwise would not have occurred.

G. Section 1605.7 Employees Ineligible to Receive Government Contributions or to Participate

One agency asked for the rationale for the provisions which require that earnings on mistaken government contributions be transferred to the appropriate undistributed earnings account. This result is required by IRS Revenue Ruling 77-200 which prohibits the return of earnings on employer contributions to the employer. The Internal Revenue Service takes the position that this limitation also applies to earnings on contributions from an employee's salary because they are made by the employer and are, therefore, also employer contributions for purposes of this Ruling. Another comment suggested that the earnings on mistaken contributions should be used by the Board to pay retroactive earnings under other sections of these regulations. The Board did not adopt this recommendation because these earnings belong to the Plan and all its participants rather than to any individual participant.

The Board added a new sentence to subsections (a) and (b) which requires that any mistaken government contribution which has not been returned to the agency within one year of the mistake must be transferred to the appropriate undistributed earnings account. These sentences were added in order to bring this section into conformity with IRS Revenue Ruling 77-200.

In addition paragraph (b) was revised to require an agency to return to the employee the full amount of the erroneous deduction despite any investment loss. Finally, a new provision was added to paragraph (b) which authorizes the employee to file a claim for compensation with his or her agency whenever an agency fails to return the full amount of an erroneous contribution undiminished by investment loss attributable to agency error.

H. Section 1605.8 Claim Procedure, Agency or Board Initiative; Time Limitation

1. Paragraph (a)(1). Two comments criticized the ten-day time period for an agency to transmit a claim alleging Board error to the Recordkeeper as being too short. This time period was not extended in the final regulation because the decision which the agency is being required to make does not address the validity of the claim. The agency is only being asked to decide whether the allegation of error relates to

agency action or to Board action. The Board wants to address employee allegations of Board error as promptly as possible and ten days should be sufficient time for the agency to make this determination and transmit the claim to the Recordkeeper. Another comment proposed that when an agency receives a claim alleging Board error, the agency should return the claim to the employee so that the employee, not the agency, would be responsible for submitting the claim to the Recordkeeper. This suggestion was not adopted because it would cause additional delay in the claim resolution process. However, this paragraph was revised to require the agency to notify the employee that the claim was being forwarded to the Recordkeeper.

2. Paragraph (a)(2). Two agencies questioned the need for the agency to provide a formal written decision to an employee where the agency agrees with his or her claim. Because there is the potential for agencies to make large scale corrections which fully satisfy employee claims, the Board decided that the requirement for a written agency decision in these cases was burdensome and unnecessary. The final regulation requires the agency to provide only a written determination on employee claims which it has denied in whole or in part.

3. Paragraph (a)(3). One agency proposed that the time limit for an employee to appeal the agency's initial decision on the claim be reduced from thirty days to ten or fifteen days. This recommendation was not adopted because some employee claims will address complex matters and a reduced appeal period would not give the employee sufficient time to evaluate the agency's determination and prepare an appeal. Two agencies asked how the end of the appeal period should be measured—the postmark on the employee's letter or receipt of the appeal by the agency. The Board's view is that any evidence indicating that an employee submitted the appeal, either to the mail or to an agency official, within this time period should be accepted as evidence that the employee filed a timely appeal.

4. Paragraph (a)(4). One comment was received on this paragraph. An agency proposed that an employee be required to file an appeal with the Board for adjudication before becoming eligible to file suit in district court. The Board rejected this proposal because it would unnecessarily lengthen the administrative process and because, in many cases, employee claims will involve disputes over facts which the

Board is not a position to adjudicate without an adversarial hearing. An administrative hearing procedure would be expensive and time consuming.

5. Subsection (b). An agency recommended that this subsection be changed to permit an agency to file an appeal with the Board on behalf of a group of agency employees. This proposal was not adopted. Agencies are encouraged to alert the Board to any errors the Board may have committed. The Board has authority under subsection (c) of this section to correct Board errors on its own initiative.

6. Subsection (d). The Board received one comment suggesting that the three-year time period within which an error could be corrected was too long. In addition, the agency criticized the point of reference (when the employee discovered or should have discovered the error) for the beginning of this time period as too vague. The final regulation provides a different time period. An error will be eligible for correction if an employee submits a claim within one year of receiving a pay slip reflecting the error or submits a claim within one year of the close of the first election period following receipt of a participant account statement reflecting the error, whichever occurs first.

I. Section 1605.9 Adjustment for Back Pay Award

One comment was received on this section suggesting that paragraph (d) be changed to provide that contributions to the Plan made by an employee from a back pay award should, for purposes of the ceiling on employee annual contributions, be credited to the year in which they should have been made rather than to year in which they were made. No change was made to this regulation because the Internal Revenue Service, which regulates this limitation, takes the position that contributions are always credited to the year in which they are made.

J. Section 1605.10 Other Retroactive Pay Adjustments

1. Subparagraph (b)(1)(iii). In certain cases, an employee's dollar amount contribution will be reduced if that contribution will exceed the percentage of pay limitations contained in 5 U.S.C. 8351 and 8432. Where this has occurred, a positive retroactive pay adjustment will require a positive adjustment to the employee's contribution. Paragraph (b)(1) was changed by adding an instruction to this effect.

2. Subsection (d). A new subsection (d) was added to deal with the problem of prorating the additional contributions generated by a pay adjustment to the

proper investment fund or funds. This will be done by using the employee's election for investment of current contributions. However, if the employee does not have a current investment election, the additional contributions will be invested in the Government Securities Investment Fund, or in the fund(s) designated by employee on an election form submitted solely for this purpose.

K. Section 1605.11 Erroneous Eligibility Classification by Official Personnel Action

The interim regulations did not address situations where an agency incorrectly determined an employee's eligibility to participate. To resolve this problem, the Board has added a new section 1605.11 which instructs the agency to give the employee the opportunity to make any of the choices relating to participation that the employee would have had if the classification error had not occurred.

L. Section 1605.12 Adjustments Rejected

This section was added to the regulations to notify the agencies that the Recordkeeper will reject any agency-initiated adjustment which would take any category of an employee's account below a zero balance. In other words, the correction will be made in full or not at all. In addition, the Board in this section is providing notice that Thrift Savings Plan funds are not available to cover any investment losses which occur as a result of agency error. The Board does not have authority to use Plan funds for this purpose.

M. Section 1605.13 Limitation on Agency Authority To Make Adjustments

This section was added to these regulations to make clear that the agencies have a positive responsibility for correcting any improper or erroneous adjustments. In addition, all adjustments must be authorized by these regulations or have been approved in advance by the Executive Director. The agencies are being provided the opportunity to request approval from the Executive Director where there is a need to make an adjustment which is appropriate but not covered by these regulations.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities. They will affect only internal government procedures for correcting

errors involving employee participation in the Thrift Savings Plan.

Paperwork Reduction Act

I certify that these regulations do not require additional reporting under the criteria of the Paperwork Reduction Act of 1980.

List of Subjects in 5 CFR Part 1605

Administrative practice and procedure, Employee benefit plans, Government employees, Pensions, Retirement.

Federal Retirement Thrift Investment Board.
Francis X. Cavanaugh,
Executive Director.

For the reasons set out in the preamble, Part 1605 of Chapter VI, Title 5, Code of Federal Regulations, is revised to read as follows:

PART 1605—CORRECTION OF ADMINISTRATIVE ERRORS

Sec.

- 1605.1 Definitions.
- 1605.2 Failure to participate or delay in participation.
- 1605.3 Insufficient contribution.
- 1605.4 Excess deduction or contribution.
- 1605.5 Delayed or erroneous posting of contributions or earnings.
- 1605.6 Agency allocation to incorrect account.
- 1605.7 Employees ineligible to receive government contributions or to participate.
- 1605.8 Claim procedure; agency or Board initiative; time limitation.
- 1605.9 Adjustment for back pay award.
- 1605.10 Other retroactive pay adjustments.
- 1605.11 Erroneous eligibility classification by official personnel action.
- 1605.12 Adjustments rejected.
- 1605.13 Limitation on agency authority to make adjustments.

Authority: 5 U.S.C. 8351 and 8474.

§ 1605.1 Definitions.

Terms used in this part shall have the following meanings:

"Account" means an employee's account with the Thrift Savings Plan.

"Agency" means the organization which took an action or committed an error with respect to an employee's participation in the Thrift Savings Plan or the organization which is responsible for taking corrective action, but does not include the Thrift Savings Plan Recordkeeper (Recordkeeper).

"Board" means the Federal Retirement Thrift Investment Board.

"Days" means calendar days.

"Employee" means "employee" as defined in 5 U.S.C. 8401(11) and 8331(1) and "Member" as defined in 5 U.S.C. 8401(20) and 8331(2).

"Executive Director" means the Executive Director of the Federal

Retirement Thrift Investment Board, as defined in 5 U.S.C. 8401(13) and as further described in 5 U.S.C. 8474.

"Recordkeeper" means the organization that is under contract to the Board to perform recordkeeping services and which is currently the National Finance Center, U.S. Department of Agriculture, P.O. Box 61500, New Orleans, Louisiana 70161-1500.

§ 1605.2 Failure to participate or delay in participation.

(a) *Actions eligible for correction.* (1) If an employee fails to participate or is delayed in participating in the Thrift Savings Plan because of reasons beyond his or her control, but not because of action or lack of action by the agency, then prospective corrective action, as the employee's request, shall be taken in accordance with paragraph (b)(1) of this section.

(2) If an employee fails to participate or is delayed in participating in the Thrift Savings Plan because of reasons that are attributable to his or her agency, the error will be corrected in accordance with paragraph (b)(2) of this section.

(b) *Correction procedures.* (1) A failure to participate or delay in participation pursuant to paragraph (a)(1) of this section shall be corrected effective not later than the first pay period beginning after the agency accepts the employee's election form. No retroactive employee contributions or government matching contributions may be made under this subparagraph.

(2) A failure to participate or delay in participation pursuant to paragraph (a)(2) of this section shall be corrected in the following manner:

(i) The agency shall correct the employee's payroll and personnel records immediately in order to assure accurate Thrift Savings Plan contributions to subsequent pay periods.

(ii) The agency shall, at the employee's election, deduct the amount of employee contributions attributable to the error from the employee's net payable salary according to an equal payment schedule agreed to by the employee. The employee must make this election within 30 days of notification of the error by the agency or forfeit the opportunity to do so. The agency may set a ceiling on the number of pay periods in which the correction may be made; however, this ceiling may not be less than two times the number of pay periods over which the error occurred. The payment schedule must begin no later than the pay period following the date of the agreed upon schedule and it may not exceed four times the number

of pay periods over which the error occurred. If the payment schedule cannot be met because the employee has insufficient net pay, the payment schedule will be suspended until the employee is able to make full payments through payroll deduction. When establishing a payment schedule for an employee, the agency will refer to his or her current election and consider whether the employee would exceed the annual ceiling for tax deferred contributions as a result of contributions relating to an error in a prior year. If this result would occur, the employee may elect to have the payment schedule established in such a manner that the payments will be, at the appropriate time, suspended until the employee is able to make payments through payroll deduction that are within the annual ceiling on tax deferred contributions. Pay periods which are prescribed in the payment schedule for which an employee is unable to make payments because of insufficient net pay, or because of the ceiling on tax deferred contributions, will not be counted against the maximum number of pay periods applicable to the schedule and the maximum number of applicable pay periods shall be extended accordingly. Employees may not make partial payments under a payment schedule.

(iii) A decision by the employee to contribute the retroactive amount may be terminated by the employee and such termination shall be deemed irrevocable. In case of separation from government service, the employee may terminate the retroactive contribution or accelerate the contribution by lump sum payment from the final salary payment (not including any lump sum annual leave payment). In case of death, the retroactive contribution of the deceased employee will be terminated as of the final salary payment.

(iv) In accordance with the payment schedule agreed to by the employee, the agency shall contribute to the employee's Thrift Savings Plan account any additional government matching contribution which the agency would have been required to contribute had the error not occurred. The matching contribution will be paid in equal installments over the payment period for the employee contribution.

(v) Any payment of the government basic contribution which the agency would have been required to contribute had the error not occurred will be made to the employee's account not later than 30 days after the date on which the agency determines that an error occurred.

(vi) Where an employee has become employed by a new agency, the former agency will continue to be responsible for determining whether there was an error applicable to the employee's Thrift Savings Plan participation while employed with the former agency and, if so, the former agency will advise the new agency of such determination and will pay any applicable government contribution to the new agency. The new agency will be responsible for payment to the Recordkeeper in accordance with the employee's payment schedule.

(vii) No earnings will be paid by the Board into an employee's Thrift Savings Plan account that would have accrued to such account but for the error causing the delay or failure of participation. However, an agency may make this type of deposit if it determines that it has the authority to spend its funds for this purpose.

(viii) The retroactive payment amount is not subject to the maximum pay period contribution limitations; however, these amounts shall be included when determining amounts subject to the annual ceiling on tax deferred contributions.

(ix) In the event that an employee does not have sufficient net pay to make all of the Thrift Savings Plan deductions, the employee's regular Thrift Savings Plan deduction shall take precedence over the employee's payment schedule contribution.

§ 1605.3 Insufficient contribution.

(a) *Errors eligible for correction.* An error of insufficient employee contribution shall be eligible for correction if an employee designated an amount or rate to be contributed from his or her net payable salary to the Thrift Savings Plan on an election form that was accepted by the appropriate agency office and the amount or rate designated was not deducted, in whole or in part, and credited to the employee's account for the eligible pay periods because of agency error. An error of insufficient government contribution shall also be corrected in accordance with this section. For example, this section will apply to situations where an employee did not receive a basic contribution or a matching contribution because of the erroneous determination of retirement system coverage or other processing error.

(b) *Correction procedure.* In the event that there is an error eligible for correction pursuant to paragraph (a) of this section, the following procedure shall apply:

(1) The agency shall correct the employee's payroll and personnel records immediately in order to assure accurate Thrift Savings Plan contributions in subsequent pay periods.

(2) The agency shall, at the employee's election, deduct the amount of employee contributions attributable to the error from the employee's net payable salary according to an equal payment schedule agreed to by the employee. The employee must make this election within 30 days of notification of the error by the agency or forfeit the opportunity to do so. The agency may set a ceiling on the number of pay periods in which the correction may be made; however, this ceiling may not be less than two times the number of pay periods over which the error occurred. This payment schedule must begin no later than the pay period following the date of the agreed upon schedule and it may not exceed four times the number of pay periods over which the error occurred. If the payment schedule cannot be met because the employee has insufficient net pay, the payment schedule will be suspended until the employee is able to make full payments through payroll deduction. When establishing a payment schedule for an employee, the agency will refer to his or her current election and consider whether the employee would exceed the annual ceiling for tax deferred contributions as a result of contributions relating to an error in a prior year. If this result would occur, the employee may elect to have the payment schedule established in such a manner that the payments will be, at the appropriate time, suspended until the employee is able to make payments through payroll deduction that are within the annual ceiling on tax deferred contributions. Pay periods which are prescribed in the payment schedule for which an employee is unable to make payments because of insufficient net pay, or because of the ceiling on tax deferred contributions, will not be counted against the maximum number of pay periods applicable to the schedule and the maximum number of applicable pay periods shall be extended accordingly. Employees may not make partial payments under a payment schedule.

(3) A decision by the employee to contribute the retroactive amount may be terminated by the employee and such termination shall be deemed irrevocable. In case of separation from government service, the employee may terminate the retroactive contribution or accelerate the contribution by lump sum payment from the final salary payment (not including any lump sum annual leave payment). In case of death, the

retroactive contribution of the deceased employee will be terminated as of the final salary payment.

(4) In accordance with the payment schedule agreed to by the employee, the agency shall contribute to the employee's Thrift Savings Plan account any additional government matching contribution which the agency would have been required to contribute had the error not occurred. The matching contribution will be paid in equal installments over the payment period for the employee contribution.

(5) Any payment of the government basic contribution which the agency would have been required to contribute had the error not occurred will be made to the employee's account not later than 30 days after the date on which the agency determines that an error occurred.

(6) Where an employee has become employed by a new agency, the former agency will continue to be responsible for determining whether there was an error applicable to the employee's Thrift Savings Plan participation while employed with the former agency and, if so, the former agency will advise the new agency of such determination and will pay any applicable government contribution to the new agency. The new agency will be responsible for payment to the Recordkeeper in accordance with the employee's payment schedule.

(7) No earnings will be paid by the Board into an employee's Thrift Savings Plan account that would have accrued to such account but for the error causing the insufficient contribution. However, an agency may make this type of deposit if it determines that it has the authority to spend its funds for this purpose.

(8) The retroactive payment amount is not subject to the maximum pay period contribution limitations; however, these amounts shall be included when determining amounts subject to the annual ceiling on tax deferred contributions.

(9) Proration of employee and government contributions to the applicable investment funds will be made using the employee's election for investment of current contributions. If an employee does not have this type of election, the contributions will be invested in the Government Securities Investment Fund or, at the employee's request, in accordance with an election form submitted solely for this purpose.

(10) In the event that an employee does not have sufficient net pay to make all of the Thrift Savings Plan deductions, the employee's regular Thrift Savings Plan deduction shall take precedence

over the employee's payment schedule contribution.

§ 1605.4 Excess deduction or contribution.

(a) *Errors eligible for correction.* An error of overdeduction shall be eligible for correction if a participant designated an amount or rate to be deducted as an allotment to the Thrift Savings Plan on an election form that was accepted by the appropriate agency office and more than the amount designated was deducted and credited to the participant's account because of agency error. This section also applies to deductions taken from the pay of an employee who did not elect to contribute, to errors of excess government contribution, and to salary overpayments.

(b) *Correction procedure.* On discovery of this error, the following actions shall take place no later than 30 days after the date on which the agency discovered the error:

(1) The agency shall correct the employee's payroll and personnel records immediately in order to assure accurate Thrift Savings Plan contributions in subsequent pay periods. Whenever there is an adjustment which involves the Common Stock Index Investment Fund or the Fixed Income Investment Fund, the agency shall query the Recordkeeper in order to determine whether there has been an investment loss attributable to the excess contribution and to determine the appropriate employee investment funds which should be adjusted to correct this error.

(2) The agency shall forward to the Recordkeeper an adjustment record(s) in the amount of the excess contribution, less any investment loss, of employee and government contributions to reduce the employee's account as appropriate. At least one adjustment record will be required for each tax year included in the adjustment period.

(3) The agency shall return the full amount of the overdeducted employee contribution to the employee and credit the agency account with the excess government contribution, less any investment loss, by appropriately crediting the routine transmittal of Plan funds to the Recordkeeper. The Thrift Savings Plan adjustment transaction will be used for this purpose. If the government's contributions is not credited to the agency's account within one year of the date of the mistake, that contribution shall remain in the employee's account.

(4) Earnings attributable to both the overdeducted employee contribution and excess government contributions

which have been paid into the employee's account will remain in the employee's account, unless the correction of this error liquidates an employee's account with respect to principal. In this case, the earnings attributable to the overdeducted employee contribution and excess government contribution will be transferred to the appropriate undistributed earnings account.

(5) The employee's agency shall correct its payroll records to reflect correct employee income information.

(6) Whenever an employee alleges that an agency made an erroneous contribution that was subsequently reduced because of investment loss, the agency shall permit the employee to file a claim for compensation for that loss in accordance with § 1605.8 of this part.

§ 1605.5 Delayed or erroneous posting of contributions or earnings.

If the Board or Recordkeeper through its error fails to post accurately contributions or earnings to an employee's account, the error will be corrected. This correction shall adjust the employee's account to place the account in the position it would have been but for the Board's or Recordkeeper's error. This section shall not apply to delayed postings due to an erroneous agency data input or a delay in the delivery of data to the Recordkeeper.

§ 1605.6 Agency allocation to incorrect account.

(a) *Errors eligible for correction.* If an agency allocates the employee or government contribution of one employee to the account of another employee, the error shall be corrected in accordance with the procedures set forth in paragraph (b) of this section.

(b) *Correction procedures.* On discovery of this error, the following actions will take place no later than 30 days following the agency's discovery of the error.

(1) The agency shall correct the payroll records of the affected employees in order to assure accurate Thrift Savings Plan contributions in subsequent pay periods.

(2) The agency shall notify the Recordkeeper of the accounts, amounts, and types of funds which were incorrectly allocated.

(3) Subject to paragraph (b)(4) of this section, the Recordkeeper will transfer the appropriate amounts and related earnings from the incorrect account to the correct account.

(4) The amounts returned by the Recordkeeper from the incorrect account to the correct account pursuant to

paragraph (b)(3) of this section shall be reduced to reflect any applicable investment loss.

(5) Whenever an employee alleges that an agency's erroneous allocation of contributions to an incorrect account were reduced by an investment loss that otherwise would not have occurred, the agency shall permit the employee to file a claim for compensation for that loss in accordance with section 1605.8 of this Part.

§ 1605.7 Employees ineligible to receive government contributions or to participate.

(a) In the event that there is a credit of government contributions to an employee who is eligible to make employee contributions but who is ineligible to receive government contributions:

(1) The agency shall recover the government contributions with an appropriate Thrift Savings Plan adjustment transaction. If the government's contribution is not credited to the agency's account within one year of the date of the mistake, that contribution shall be transferred to the appropriate undistributed earnings account.

(2) The Board shall transfer any earnings on the government contributions from the employee's account to the appropriate undistributed earnings account.

(b) In the event there is a credit of funds to an employee who is ineligible to participate in the Thrift Savings Plan:

(1) The agency shall forward to the Recordkeeper an adjustment record(s) in the amount of the erroneous contribution, less any investment loss, of employee and government contributions to reduce the employee's account as appropriate. At least one adjustment record will be required for each tax year included in the adjustment period.

(2) The agency shall return the full amount of the erroneous employee contribution to the employee and credit the agency account with any erroneous government contribution, less any investment loss, by appropriately crediting the routine transmittal of Plan funds to the Recordkeeper. The Thrift Savings Plan adjustment transaction will be used for this purpose. If the government's contribution is not credited to the agency's account within one year of the date of the mistake, that contribution shall be transferred to the appropriate undistributed earnings account.

(3) The Board shall transfer any earnings on employee contributions and government contributions to the

appropriate undistributed earnings account.

§ 1605.8 Claim procedure; agency or Board initiative; time limitation.

(a) *Agency procedure.* Each agency responsible for processing employee elections to participate in the Thrift Savings Plan shall establish the following procedure which allows an employee to present a claim for correction under this Part:

(1) The agency shall review all employee claims in order to determine whether they relate to an error which may have been made by the agency or by the Board. A claim which relates to possible Board errors shall be transmitted by the agency to the Board's Recordkeeper within 10 days of the agency's receipt of a written claim from the employee. The employee shall be provided notice of this referral at the time it is made.

(2) The agency shall review a claim and provide the employee with a decision within 30 days of its receipt of the employee's written claim. The agency's decision to deny a claim in whole or in part shall be in writing and shall contain the following information—

(i) The agency's determination on the claim and the reasons therefor, including references to applicable statutes or regulations;

(ii) A description of any additional material or information necessary for the employee to perfect the claim and an explanation of why such material or information is necessary; and

(iii) Appropriate information as to the steps to be taken, as set forth below, if the employee wishes to appeal the agency decision on the claim.

(3) Within 30 days after receipt of an agency decision denying a claim, an employee may appeal the agency decision. An appeal shall be in writing and addressed to the agency official designated in the agency's decision. The employee's appeal may contain any documents or comments the employee deems relevant to the claim.

(4) The agency shall make a decision on the employee's appeal not later than 30 days after its receipt of the appeal. The agency's decision on the appeal shall be written in an understandable manner and shall include the reasons therefor as well as references to applicable statutes and regulations. If the decision on the employee's appeal is not made within this 30 day time period, or if the decision on the appeal denies the employee's claim, in whole or in part, the employee shall have exhausted his or her administrative remedy and shall be eligible to file suit in the

appropriate Federal district court pursuant to U.S.C. 8477. There is no administrative appeal of an agency final decision to the Board.

(b) *Board procedure.* The Board shall provide the following procedure for reviewing claims relating to possible errors on the part of the Board:

(1) On receipt of a claim transmitted by an agency in accordance with paragraph (a)(1) of this section, the Recordkeeper shall review the claim and provide the employee and the agency with a decision within 30 days of its receipt of the claim. This decision shall be written in an understandable manner and shall contain the following information:

(i) The Recordkeeper's determination on the claim and the reasons therefor, including reference to applicable statutes or regulations;

(ii) In the case of a denial of the claim, in whole or in part, a description of any additional material or information necessary for the employee to perfect the claim and an explanation of why such material or information is necessary, and

(iii) In the case of a denial of the claim, in whole or in part, appropriate information as to the steps to be taken, as set forth below, if the employee wishes to appeal the Recordkeeper's decision on the claim.

(2) Within 30 days after the receipt of the Recordkeeper's decision denying a claim, an employee may appeal the decision. The appeal shall be in writing and addressed to the Executive Director, Federal Retirement Thrift Investment Board, Post Office Box 18899, Washington, DC 20036, and may contain any documents or comments the employee deems relevant to the claim.

(3) The Executive Director shall make a decision on the employee's appeal not later than 30 days after the Board's receipt of the appeal. This decision shall be written in an understandable manner and shall include the reasons therefor as well as references to applicable statutes and regulations. If the decision on the employee's appeal is not made within this 30 day time period, or if the decision denies the employee's claim, in whole or in part, the employee shall have exhausted his or her administrative remedy and shall be eligible to file suit in the appropriate Federal district court pursuant to 5 U.S.C. 8477.

(c) *Agency or Board initiative.* Errors or actions covered by this Part may be corrected, in the manner and to the extent provided in this Part, at the initiative of the agency or of the Board regardless of whether an employee submits a claim pursuant to this section.

(d) *Time limitation.* An error or action described in this Part shall only be eligible for correction pursuant to paragraphs (a) and (b) of this section if the employee submits a claim within 1) one year of his/her receipt of a pay slip or other document reflecting the error, or 2) within one year of the close of the first election period following his/her receipt of Thrift Savings Plan Participant Statement (Form TSP-8) reflecting the error, whichever occurs first. This time limitation does not apply to agency or Board initiated corrections pursuant to paragraph (c) of this section.

§ 1605.9 Adjustment for back pay award.

(a) *General.* The purpose of this section is to make an employee receiving a back pay award whole with respect to participation in the Thrift Savings Plan in connection with employee contributions, government contributions, and elections which he or she would have otherwise been able to make had the unwarranted or unjustified personnel action not occurred.

(b) *Continuous service.* Employees who receive a retroactive pay adjustment pursuant to 5 U.S.C. 5596 for a period of time when they were not separated from government service, will only receive an adjustment to applicable Thrift Savings Plan contributions if they had designated a percentage of basic pay as a contribution or if they had designated a dollar amount contribution which had been reduced (because of the percentage limitations on employee contributions contained in 5 U.S.C. 8351 and 8432) as a consequence of the unwarranted or unjustified personnel action. In those cases where an adjustment is required, the agency shall compute and forward to the Recordkeeper such additional amounts attributable to the employee contribution and, if applicable, the government basic contribution and government matching contributions.

(c) *Erroneous separation.* If an employee receives a back pay adjustment pursuant to 5 U.S.C. 5596 for a period of time when he or she was erroneously separated from government service, the agency shall—

(1) Give the employee the opportunity to make any elections, including termination, in the same manner the employee could have chosen had the erroneous separation not occurred;

(2) Compute and forward to the Recordkeeper such amounts of employee contributions and, if applicable, the government basic contribution and government matching contributions which are consistent with

the decisions the employee made pursuant to paragraph (c)(1) of this section; and

(3) Make routine contributions for future pay periods in accordance with the employee's current Thrift Savings Plan election form.

(d) In making adjustments in accordance with paragraphs (b) and (c) of this section, agencies shall ensure that the employee's contribution does not exceed the ceiling on employee contributions for any calendar year found in 26 U.S.C. 402(g)(1). For purposes of making this calculation, employee contributions shall be credited to the calendar year in which they are made.

§ 1605.10 Other retroactive pay adjustments.

(a) *Actions eligible for correction.* Whenever an agency is required to make a retroactive pay adjustment, other than a pay adjustment covered by § 1605.9 of this Part, the agency shall also make an adjustment to the employee's Thrift Savings Plan contributions in the manner prescribed in paragraph (b) of this section.

(b) *Correction procedure.* In the event that there is a retroactive upward pay adjustment pursuant to paragraph (a) of this section, the following procedure shall apply:

(1) The agency shall—

(i) If applicable, compute the adjustment to the government basic contribution for all employees who were eligible to participate in the Thrift Savings Plan during all or part of the affected period;

(ii) Compute additional employee contributions for employees participating in the Thrift Savings Plan who elected to contribute a percentage of basic pay during all or part of the affected period;

(iii) Compute additional employee contributions for employees participating in the Thrift Saving Plan who elected to contribute a dollar amount contribution which had been

reduced (because of the percentage limitations on employee contributions contained in 5 U.S.C. 8351 and 8432) as a consequence of the previous salary payment.

(iv) If applicable, compute additional government matching contributions for employees; and

(v) Forward the amounts computed under paragraphs (b)(1), (i), (ii), (iii), and (iv) of this section to the Recordkeeper.

(2) The Recordkeeper shall—

(i) Credit the retroactive adjustment amounts to the appropriate active accounts;

(ii) With respect to former employees who do not have active Thrift Savings Plan accounts, allocate these retroactive amounts to the Government Securities Investment Fund for investment by the Board;

(iii) Pay the retroactive amounts (and earnings attributable to their investment) to those former employees, and provide appropriate documentation, at the following monthly scheduled payment of withdrawals from the Thrift Savings Plan;

(iv) Forfeit immediately to the undistributed earnings account of the Government Securities Investment Fund any payments returned as undeliverable and pay such amounts and attributable earnings to former employees who later file an appropriate and timely claim under section 1605.8 of this part;

(v) Not pay retroactive earnings that are based on a retroactive pay adjustment to any former employee or post such earnings to the account of any current employee;

(vi) Not make any payments to former employees which are less than one dollar.

(c) In making adjustments in accordance with paragraph (b) of this section, agencies shall ensure that the employee's contribution does not exceed the ceiling on employee contributions for any calendar year found in 26 U.S.C. 402(g)(1). For purposes of making this calculation, employee contributions

shall be credited to the calendar year in which they are made.

(d) Proration of employee and government contributions to the applicable investment funds for active employees will be made using the employee's election for investment of current contributions. If an employee does not have this type of election, the contributions will be invested in the Government Securities Investment Fund or, at the employee's request, in accordance with an election form submitted solely for this purpose.

§ 1605.11 Erroneous eligibility classification by official personnel action.

If an agency makes an erroneous determination of an employee's retirement system coverage, the employee shall be given the opportunity to make any elections, including termination, in the same manner the employee could have chosen had the erroneous classification not occurred.

§ 1605.12 Adjustments rejected.

The Recordkeeper will reject any agency adjustments which would take any category of an employee's account below a zero balance. Examples of situations which may require an adjustment rejection are where the employee's account has been reduced because of a garnishment or loan, or where the account has been cleared due to separation of the employee from government service. Furthermore, any investment losses which are a consequence of agency errors will not be covered by Thrift Savings Plan funds.

§ 1605.13 Limitation on agency authority to make adjustments.

Agencies are responsible for correcting any improper or erroneous adjustments and they may not make an adjustment to an employee's Thrift Savings Plan account unless it is authorized by this Part or approved in advance by the Executive Director.

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Jukebox

**Friday
December 4, 1987**

Part IV

**Copyright Royalty
Tribunal**

**Final Determination of the Distribution of
the 1985 Jukebox Royalty Fund; Notice**

COPYRIGHT ROYALTY TRIBUNAL**[CRT Docket No. 87-1-85JD]****Final Determination of the Distribution of the 1985 Jukebox Royalty Fund****AGENCY:** Copyright Royalty Tribunal.**ACTION:** Notice of final determination.

SUMMARY: The Tribunal announces the adoption of its final determination in the proceeding concerning the distribution to certain copyright owners and performing rights societies of jukebox royalty fees deposited for 1985 performances.

FOR FURTHER INFORMATION CONTACT: Robert Cassler, General Counsel, Copyright Royalty Tribunal, 1111 20th Street, NW., Suite 450, Washington, DC 20036.

SUPPLEMENTARY INFORMATION:**Authority**

17 U.S.C. 116(c)(3) authorizes the Copyright Royalty Tribunal (Tribunal) to distribute annually royalty fees paid by jukebox operators to certain copyright owners and performing rights societies. First, the Tribunal is to assess the claims of, and make appropriate awards to, "every copyright owner not affiliated with a performing rights society." 17 U.S.C. 116(c)(4)(A). Second, the remainder is to be distributed to "the performing rights societies * * * as they shall by agreement stipulate among themselves, or if they fail to agree, the pro rata share to which such performing rights societies prove entitlement." 17 U.S.C. 116(c)(4)(B).

The Claimants and the Controversy

In this proceeding, the Tribunal takes up the distribution of the royalty fees deposited by jukebox operators for the calendar year 1985.

Five parties filed claims in the 1985 proceeding: the American Society of Composers, Authors and Publishers (ASCAP), Broadcast Music, Inc. (BMI), SESAC, Inc. (SESAC), Asociacion de Compositores y Editores de Musica Latinoamericana (ACEMLA), and Italian Book Corporation (IBC).

ASCAP, BMI and SESAC (hereinafter A/B/S) reached an agreement for division of the jukebox royalties among themselves, and decided to prosecute their claims jointly. *Justification of Claim*, filed November 3, 1986. ACEMLA and IBC (hereinafter ACEMLA/IBC) reached an agreement for division of the jukebox royalties among themselves, and decided to prosecute their claims jointly. *Joint Justification Statement of ACEMLA and IBC*, dated November 3, 1986.

In their statements of justification of claim, A/B/S jointly claimed 100% of the fund, and ACEMLA/IBC jointly claimed 12% of the fund. *Id.* In its final pleading in this proceeding, A/B/S claimed that ACEMLA/IBC was entitled to no more than 0.01807% of the fund, and that A/B/S was entitled to the rest, 99.98193%. A/B/S Reply Findings, par. 33. In its final pleading in this proceeding, ACEMLA/IBC claimed 10 to 13% of the fund. ACEMLA/IBC Reply Findings, p. 17.

Procedural Requirements of This Proceeding

As stated above, section 116 of the Copyright Act requires the Tribunal to take up the claims of copyright owners first, and the claims of the performing rights societies second. ASCAP, BMI and SESAC have been defined by Congress as performing rights societies, so no further inquiry into their status is required. 17 U.S.C. 116(e)(3). ACEMLA and IBC were found by the Tribunal in the consolidated 1982/1983 jukebox distribution proceeding not to be performing rights societies. 50 FR 47577 (November 19, 1985), *aff'd*, *ACEMLA v. Copyright Royalty Tribunal*, 809 F.2d 926 (D.C. Cir. 1987).¹ ACEMLA relitigated the question in the 1984 proceeding and was found once again not to be a performing rights society for 1984. 51 FR 43455 (December 2, 1986). In this proceeding, ACEMLA and IBC have relitigated their status, claiming that they are performing rights societies, not copyright owners.

The effect of whether ACEMLA and/or IBC are performing rights societies is procedural. If they are copyright owners, they have the burden of going forward with their evidence as to their entitlement alone. If they are performing rights societies, they and ASCAP, BMI and SESAC must each go forward to prove their entitlements, so long as no settlement among all the performing rights societies exists.

Previous findings by the Tribunal that ACEMLA and IBC were not performing rights societies do not collaterally stop ACEMLA and IBC from relitigating their status in subsequent proceedings, because it is possible that in any calendar year, ACEMLA and/or IBC may become performing rights societies.

Hence, in this proceeding, it was necessary to take evidence as to the status of ACEMLA and IBC, as well as the entitlements to the jukebox funds of the five claimants.

¹ The finding that IBC was not a performing rights society was based upon a stipulation of all parties, not on a full litigation of the facts. See discussion below in the first Conclusions of Law section.

Background and Chronology

On December 9, 1986, the Tribunal published a notice declaring that a controversy existed concerning the distribution of the 1985 jukebox royalty fund, effective December 10, 1986. In the same notice, the Tribunal ordered a partial distribution to ASCAP, BMI and SESAC of 95% of the 1985 jukebox royalty fund upon the condition that in the event the Tribunal determined that ACEMLA/IBC's entitlement exceeded 5%, A/B/S would reimburse ACEMLA/IBC the excess amount plus interest. 51 FR 44331.

By Order, dated January 16, 1987, the Tribunal announced that it would conduct the hearing of the 1985 jukebox distribution proceeding in two phases and directed the parties to file their written direct cases in two segments as follows: the first segment to include, for ACEMLA and IBC, proof of their status under section 116 of the Copyright Act, whether "copyright owner" or "performing rights society," and the second segment to include, for all parties, proofs of their respective entitlement.

The written direct cases were filed April 16, 1987. The Tribunal conducted six days of evidentiary hearings. A/B/S presented its direct case on May 11, 1987. On May 18, 1987, ACEMLA presented its evidence on the issue of the performing rights society status of ACEMLA. On May 19, 1987, IBC presented its evidence on its status, then secondly, its evidence on its entitlement. ACEMLA then presented its evidence on entitlement.

On June 5, 1987, the parties filed their written rebuttal cases. On June 22, 1987, ACEMLA/IBC presented its rebuttal case. Additional direct case testimony from A/B/S was heard that day in response to a request from the Tribunal for additional evidence.

On June 23 and 24, 1987, A/B/S presented its rebuttal case. With the permission of the Tribunal, ACEMLA/IBC was granted leave to file surrebuttal, which was filed June 30, 1987.

By Order, dated July 2, 1987, the record of the proceeding was closed. The parties filed their Proposed Findings of Fact and Conclusions of Law on July 16, 1987. Reply Proposed Findings of Fact and Conclusions of Law were filed on July 24, 1987.

Findings of Fact**Status of ACEMLA**

Previous Findings. The Tribunal took evidence regarding the status, organization and practices of ACEMLA

in the 1982/1983 consolidated proceeding and in the 1984 proceeding. All of the facts of the 1982/1983 jukebox distribution proceeding and the 1984 jukebox distribution proceeding are hereby incorporated by reference into the 1985 jukebox distribution proceeding final determination. 50 FR 47577; 51 FR 43455.

Current Findings—1985 Proceeding. In its relitigation of the Tribunal's determination that ACEMLA was not a performing rights society, ACEMLA attempted in the 1985 proceeding to bolster its previous showings in the following areas:

Agreement with copyright owners and/or performing rights societies. L. Raul Bernard (Bernard), president of ACEMLA, stated that in November, 1986, ACEMLA entered into an agreement with the Sociedad Puertorriquena de Autores, Compositores y Editores de Musica, Inc. (SPACEM), an association of composers in Puerto Rico, to collect and distribute performing rights royalties, retroactive to April 1, 1985. ACEMLA Ex. 1, p. 1; ACEMLA Ex. 25, Att. A. In rebuttal, ASCAP asserted that it had a pre-existing contract with SPACEM for 1985. A/B/S Rebuttal, Testimony of Paul S. Adler, pp. 7-9. Further, BMI asserted that in 1985, it licensed the rights to over 900 songs composed by approximately 60 of the writers who are asserted to belong to SPACEM. A/B/S Ex. 33R; Tr. 446-447.

Bernard stated that in October, 1986, ACEMLA established an office in the Dominican Republic, and that ACEMLA is now the only Dominican Republic organization authorized under law to act as a performing rights society. ACEMLA Direct, Ex. 1, p. 2. Bernard had no documentation to support his assertion of being the only authorized performing rights society in the Dominican Republic. Tr. 129. Bernard made no attempt to relate these assertions of events taking place in 1986-1987 to 1985. ACEMLA Direct, Ex. 1.

ACEMLA submitted contracts between Latin American Music Co., Inc. (LAMCO) and 25 different individual composers entered into between 1970 and 1985 (contracts entered into prior to April, 1981 were with Latin American Music, a sole proprietorship owned by Bernard which was a predecessor company to LAMCO). Typically, these contracts provide that the composer assign to LAMCO "the entire exclusive right to publicly perform" the music assigned. ACEMLA Ex. 24.

ACEMLA also claimed it has agreements with SELEMUSICA, a Venezuelan publisher, through its agreement with Westside Music Publishers, Inc. of New York, with

Discofinia, an Argentinian publisher, with PERUMUSICA and Corporacion Musical Latino, Peruvian publishers, and with HONY of Mexico. ACEMLA Direct, Ex. 1, pp. 2-3. Except for three titles, any agreement as to other songs with PERUMUSICA was an oral agreement. Tr. 132. Similarly, the agreement with HONY of Mexico was oral. Tr. 134.

Licensing Activity. On September 29, 1986, ACEMLA entered into a licensing agreement with radio station WNWK, Newark, New Jersey, pursuant to which the radio station acknowledged it broadcasted some musical works under ACEMLA's control between September, 1983 and September, 1986 and agreed to a retroactive license during that three-year period at a rate of \$1500 per year. 1984 ACEMLA Ex. 15, p. 1 (excluded from the 1984 record for untimeliness, admitted for first time in the 1985 proceeding).

ACEMLA attempted unsuccessfully to obtain licenses in 1985 from WXTV, Channel 41, Secaucus, New Jersey; WADO, New York, New York; WNJU-TV, Newark, New Jersey; WSKQ, New York, New York; WJIT, New York, New York; KFLR, Phoenix, Arizona; KFLT, Tucson, Arizona, and KFLQ, Albuquerque, New Mexico; WKDM, Carlstadt, New Jersey; KDOS-FM, Fremont, California; and KGST, Fresno, California. ACEMLA Ex. 3.

Other features. Bernard stated ACEMLA collected in 1986 its first royalties for the public performance of music from radio station WNWK for music broadcast during the years 1983-1986. ACEMLA Ex. 1, p. 4. ACEMLA also claimed that it received, during 1987, payments from the jukebox fund maintained by the U.S. Government as a result of awards made by the Tribunal for jukebox play of ACEMLA's compositions during 1982 and 1983. *Id.* These awards were made to LAMCO, a music publishing company, not to ACEMLA. 51 FR 43460.

ACEMLA made no distributions during 1985. ACEMLA Ex. 1, pp. 4-5.

Bernard stated that on March 11, 1987, LAMCO, ACEMLA, and Bernard filed a civil action in the U.S. District Court for the District of New Jersey against Command Broadcast Associates, d/b/a WADO Radio, alleging copyright infringement during 1985, as well as other years. ACEMLA Ex. 1, p. 3. Bernard also stated that on April 14, 1987, LAMCO, ACEMLA, and Bernard filed a suit in the U.S. District Court for the District of New Jersey against Infinity Broadcasting Co., Inc., d/b/a WJIT, alleging copyright infringement during 1985 and other years. *Id.*, p. 4.

Staff of ACEMLA. According to Bernard, the staff of ACEMLA has

remained the same size as in the period 1982-1984, five employees. Tr. 104. These employees work for Bernard's record company, and music publishing company, as well as in the performing rights area. When asked by the Tribunal whether there are any officers of ACEMLA besides Bernard, whether there are any employees who work specifically for ACEMLA, and how many hours Bernard, his wife, and his employees devote to ACEMLA, Bernard stated either it was privileged information, or answered the questions in the most general way. Tr. 104-114. Bernard was told by the Tribunal that the Tribunal can only make determinations based upon what it is presented. Tr. 105, 114.

Assertion of attributes similar to SESAC. ACEMLA introduced a blank SESAC-publisher form agreement which has clauses which assign to SESAC, in addition to the right to license the performing right in nondramatic musical works, the licensing of dramatic musical works, mechanical rights and synchronization rights. ACEMLA Ex. 15RX. A/B/S concedes that SESAC's activities extend beyond performing rights to include mechanical and synchronization rights. A/B/S Proposed Findings, par. 63.

Status of IBC

Italian Book Company was formed in 1910. Tr. 231. Italian Book Company, and other organizations, such as DeMartino Italian Music Corporation, Libria DeMartino, Inc., and ItalAmerica Music Publishers, Inc. merged to form IBC some time between 1968 and 1970. Tr. 231, 248.

IBC has agreements with Italian music publishers in which, in the United States and Canada, IBC is free to assign its songs to other publishers and license all aspects of copyrights for the publishers it represents. Tr. 240. IBC stated it represented two copyright owners directly. Tr. 262. On the basis of these agreements, IBC represented that it has about 25,000 Italian-language songs composed between 1900 and 1972 in its repertory. IBC Ex. 1, p. 1.

Under its agreements with Italian publishers, 10% of all license fees collected is deducted for costs, and the remainder is split equally between IBC and the Italian publisher. Tr. 238-239. The Italian publishers are not members or affiliates of IBC. Tr. 287. Royalties are sent by IBC to the publisher only, not to the composer. Tr. 287-288.

IBC styles itself a "small family business." Tr. 265. It makes no organizational or structural distinctions between its asserted performing rights

society operation and its publishing and subpublishing operation. Tr. 265. IBC has no departments or divisions. *Id.*

IBC received about \$6,000 in license fees from about 10 or 11 radio stations in 1985. Tr. 266-267. IBC did not license the public performance of its music to restaurants, theaters, or concert halls in 1985, except perhaps for one or two instances, in which the fee might have been \$50 or \$60. Tr. 267-270. IBC did not distribute any royalties in 1985. IBC Ex. 1, p. 1; Tr. 218.

In the past, IBC has been a publisher member of ASCAP and a publisher affiliate of BMI. Tr. 237. In the view of the owner of IBC, Frank Tudisco, IBC is both a performing rights society and a music publisher. Tr. 248. IBC has listed itself sometimes as a music publisher in Billboard's *International Buyers' Guide*, and sometimes as a licensing organization. In the 1971-1972 edition, IBC listed itself as a music publisher. A/B/S Ex. 20X; Tr. 259. In the 1982-1986 editions, IBC listed itself as a licensing organization. IBC Ex. 5R. The Billboard publication is published yearly and the information is based upon information solicited from the organizations which appear therein. *Id.*

During the 1979/1980 jukebox distribution proceeding, IBC represented to the Tribunal that it was a performing rights society, and the Tribunal, considering IBC's status not necessary to the determination of IBC's royalty award, accepted IBC's assertions without further inquiry. 47 FR 18406 (1982). In the appeal taken by ACEMLA of the 1982 jukebox distribution, however, the Court of Appeals found that determining the status of the claimants is necessary to a proper handling of the jukebox fund distribution, and remanded the 1982 jukebox royalty distribution to the Tribunal for further examination by the Tribunal of the status of ACEMLA (and by implication, the status of any future claimants, such as IBC). *ACEMLA, Latin American Music and Latin American Music, Inc. v. Copyright Royalty Tribunal*, 763 F. 2d 101 (2d Cir. 1985).

In the 1982/1983 consolidated jukebox distribution proceeding, the Tribunal received a stipulation signed by ASCAP, BMI, SESAC, ACEMLA, and IBC, representing that IBC was a copyright owner and not a performing rights society. 50 FR 47577, 47578, 47581. In this proceeding, IBC has not presented any evidence that any structural or organizational changes were made within IBC to account for any change in the representation of its status over the years. IBC Direct Case.

Rebuttal of A/B/S Regarding Status of ACEMLA and IBC

Paul S. Adler (Adler), Director of Membership for ASCAP, testified on behalf of A/B/S to rebut the assertions by ACEMLA and IBC that they are performing rights societies. Reb. Test. of Adler. In Adler's view, the salient features of a performing rights society are: (1) It is an organization separate and independent of any publisher or writer; (2) it represents a diverse range of writers and publishers; (3) it has a staff of a size sufficient to operate in the territory for which it claims to administer rights; (4) it licenses a wide range of users throughout that territory, with sufficient administrative and legal staff to police meaningfully the rights it licenses; (5) it has a well-defined, published royalty distribution system for writers as well as publishers; (6) in the normal course, it pays the writer and publisher groups their royalties directly and separately; and (7) it makes such royalty payments in a regularized manner. *Id.*, pp. 1-2.

In Adler's view, ACEMLA and IBC have no distribution system at all; what they have is a form of publisher-subpublisher arrangement, which includes a provision that the subpublisher will collect performing rights income directly from licensees, rather than obtaining it through a performing rights society. *Id.*, pp. 2-3. The United States subpublisher collects United States royalties, keeps a percentage, and remits payments to the foreign publisher as they may agree. In such an arrangement, the foreign writer has no relationship with the U.S. subpublisher at all; the writer gets paid from the original publisher out of the money the publisher receives. *Id.*, p. 4.

Conclusions of Law

ACEMLA Was Not a Performing Rights Society in 1985. IBC Was Not a Performing Rights Society in 1985

The Tribunal concluded in the 1982/1983 jukebox distribution proceeding, and again in the 1984 jukebox distribution proceeding that ACEMLA was not a performing rights society during those years. The Tribunal found that Mr. Bernard had not taken any structural steps in 1982-1984 to create a performing rights society aside from filing for ACEMLA to be the assumed name of LAMCO. We found in the last proceeding that the structural device of "assumed name" was an insufficient step. We stated,

The law and logic dictate that an assumed name is not a separate entity from its original name. Additionally, here the use of this device establishes a very difficult

contradiction. Mr. Bernard claims that LAMCO is a music publisher, and that ACEMLA is a performing rights society, and that they must be considered different. But he also claims that ACEMLA is a corporation by virtue of it being the assumed name of LAMCO, and he asserts that ACEMLA has obtained the rights to represent the music obtained by LAMCO without any transfer documents because ACEMLA and LAMCO are the same. Evidently, sometimes ACEMLA is different than LAMCO and sometimes they are one and the same. 51 FR 43457

We required that one part of finding ACEMLA to be a performing rights society would be a finding that ACEMLA is at least independent enough of copyright owners to have its own organizational papers and structure. In 1985, ACEMLA took no further structural steps to create a performing rights society, and therefore, it fails to meet the first part of the definition of a performing rights society in the Copyright Act, "An association or corporation * * *

ACEMLA's attempt at bolstering its 1982-1984 showings in the 1985 proceeding were unavailing. ACEMLA claims it has new agreements with SPACEM, Discofinia, PERUMUSICA, Corporacion Musical Latino, HONY and with 25 individual composers. A/B/S attempted to diminish the effect of these additional agreements by asserting that ASCAP had the pertinent agreement with SPACEM for 1985, and that, except for three titles belonging to PERUMUSICA, the agreements with PERUMUSICA and with HONY were oral agreements, and therefore, ineffective under the Copyright Act. It is unnecessary for the Tribunal to rule on these cross-assertions in this instance, because it is the nature of the agreements, not the number of them, that is important to the question of whether ACEMLA is a performing rights society.

Regarding the nature of these agreements, these agreements are with LAMCO, the music publisher. In the case of the 25 individual composers, the Tribunal adopted ACEMLA/IBC's proposed findings verbatim, "ACEMLA submitted contracts between LAMCO and 25 different composers entered into between 1970 and 1985. Typically, these contracts provide that the composer assign to LAMCO 'the entire exclusive right to publicly perform' the music assigned." ACEMLA/IBC Proposed Findings, par. 7. These individual composers are neither members nor affiliates of ACEMLA; they have entered into a contract with a music publisher in which the public performing right has been assigned. As to the other contracts, in earlier proceedings, Mr. Bernard

testified that the performing rights obtained by various contracts with Latin American Music, LAMCO, or International Music Co. were assigned to ACEMLA, but there was no documentation to support this. Mr. Bernard explained that any agreement with LAMCO would act automatically as an authorization to ACEMLA, because ACEMLA is an assumed name of LAMCO.

This is an insufficient explanation. Prospective members or affiliates of ACEMLA must have the cognition that they are becoming members or affiliates of a society, and, in addition, oral assignment of rights is ineffective under the Copyright Act. 17 U.S.C. 204(a). ACEMLA has done nothing in 1985 to improve upon this deficiency.

ACEMLA's assertion that it has established an office in the Dominican Republic and that it is now the only Dominican Republic organization authorized under law to act as a performing rights society is undocumented, and if true, pertains to events occurring in 1986-1987 and no attempt to show the relevance to 1985 was made. Additionally, the opinion of the Dominican Republic, although useful information for the Tribunal, is not binding on the Tribunal.

ACEMLA also points to licensing activity and to enforcement activity to show that it has the attributes of ASCAP, BMI and SESAC. It entered into an agreement on September 29, 1986 with WNWK, Newark, New Jersey, to pay ACEMLA a license for use of ACEMLA's music between September, 1983 and September, 1986. It stated it instituted two suits in 1987 alleging infringement by WADO and WJIT during 1985 and other years. A/B/S argue against the relation back nature of this evidence, pointing out that the license agreement occurred in 1986 and the infringement actions occurred in 1987. Again, it is not necessary for the Tribunal to resolve these arguments, because it is not the number of licenses ACEMLA succeeds in obtaining or the number of infringement suits it initiates, but whether ACEMLA obtained these licenses and instituted these suits as a music publisher or subpublisher, or as a performing rights society.

At the close of the oral testimony, the Tribunal instructed the claimants to file their opinions as to the difference between copyright owners and performing rights societies. In the 1982/1983 consolidated jukebox distribution proceeding, the Tribunal stated its opinion that a music publisher is not a performing rights society by the mere fact that it may license music, or that it may enforce its copyright. We stated,

A copyright owner, before he or she assigns the rights in the copyright to someone else, may enforce the performing rights. So may a music publishing company after it has been assigned the rights from a copyright owner, and so may a U.S. subpublisher. In fact, Congress recognized this by among other things establishing the first category of copyright owners to collect royalties for performing rights on jukeboxes and then the second category of performing rights society. Mr. Bernard's view of the law would make every individual copyright owner or music publisher a performing rights society. 50 FR 47581

ACEMLA/IBC answered the Tribunal's request by proffering this definition, "any association or corporation which controls enough music to command long-term licenses from users desiring such licenses for legitimate economic reasons and which distributes the revenues from those licenses to others is a Performing Rights Society." ACEMLA/IBC Proposed Findings, par. 55. The Tribunal disagrees with this definition. Among other things it seems to place its emphasis on the size of the music catalogue, and the value of that catalogue sufficient to command long-term licenses, thereby introducing a question of "bigness" that the Tribunal has rejected. 50 FR 47581. It also places emphasis on distribution of revenues. The Tribunal agrees that this is important, but by its own definition, ACEMLA would fail to meet the test, because it has not yet made a distribution to any individual or entity with which it has an association. Finally, it is a definition which could be met by a music publisher as well as a performing rights society, and hence, misses the distinction the Tribunal believes Congress intended.

The Tribunal agrees with the points made by Mr. Adler, witness for A/B/S, that the difference between a performing rights society and a music publisher or subpublisher is that a performing rights society is an organization separate and independent of any publisher or writer, that it has a well-defined, published royalty distribution system for writers as well as publishers, that in the normal course, it pays the writers and publishers groups their royalties directly and separately and it makes such royalty payments in a regularized manner. In a publisher-subpublisher relationship, the subpublisher in the United States will collect the pertinent royalties directly from the licensees, keep a percentage, and remit payment back to the foreign publisher as they may agree. The writer gets paid from the original publisher out of the money the publisher receives.

A/B/S also urged upon the Tribunal that the difference between a

subpublisher and a performing rights society is one of size. Although not necessarily stating that a purported society must have the size of ASCAP, BMI or SESAC, A/B/S does argue that a purported society should have a staff of a size sufficient to operate in the territory for which it claims to administer rights, and to police meaningfully the rights it licenses. The Tribunal has rejected the argument of "bigness," but it has been concerned with whether ACEMLA has the resources to function at all. It has at most five employees. These five employees are shared with the record company and the music publishing company, and Mr. Bernard declined to answer the Tribunal's questions as to how these employees are used, or how much time they devote to ACEMLA matters. The Tribunal stated at that time that without the cooperation of the witness, an adverse conclusion would most likely result. Here, in view of the entire record, we believe an adverse conclusion is warranted, and that is, that ACEMLA does not have sufficient employees to function as a performing rights society.

ACEMLA has three final arguments: (1) That because SESAC, like ACEMLA, also carries out the licensing of mechanical rights and synchronization rights, therefore the Tribunal's insistence on a structural differentiation between the performing rights society functions of ACEMLA and the music publishing functions of ACEMLA is either arbitrary or must be applied equally to SESAC; (2) that the Tribunal's findings that ACEMLA is not a performing rights society unduly inhibits emerging organizations such as ACEMLA from entering the performing rights society business as a competitor to the oligopolies of ASCAP, BMI and SESAC, and that as a federal government agency, the Tribunal is obligated to conduct its proceedings in a manner to enhance competition, rather than raise artificial barriers to entry; (3) that section 116 has created two classes of claimants with dramatically different and unequal burdens of proceeding, and that these classifications violate the equal protection requirements of the U.S. Constitution.

Regarding ACEMLA's reference to SESAC's activities, while SESAC may at times carry on some functions of a music publisher, it was recognized by Congress as a performing rights society, and the record indicates that it chiefly collects the performing rights royalties on behalf of its many affiliates. On the other hand, LAMCO is a music publishing company—the owner of

copyrights—which has endeavored to start a performing rights society, ACEMLA. It wants to achieve this by transferring from LAMCO to ACEMLA the license to collect performing rights royalties, yet without ACEMLA constituting a different entity, the "transfer" is a fiction. ACEMLA must be more than another name for LAMCO. It must essentially be a performing rights society.

The seeming equality between ACEMLA and SESAC which ACEMLA believes was shown by the blank SESAC contract form was not shown at all. There are times when businesses will perform functions outside of their essential area of interest. For example, grocery stores will carry over-the-counter drugs, and conversely, a drug store will sell milk and bread. In any factual situation which is not entirely clear-cut, what the reviewing agency must resolve is the essential nature of the entities before it. Here, we have resolved that ACEMLA is essentially a music publisher and SESAC is essentially a performing rights society, and that finding is undisturbed by any activities in which SESAC may engage outside of the performing rights area.

ACEMLA's argument that the Tribunal has antitrust responsibilities fails for lack of a foundation. The Tribunal has no regulatory powers in the music industry, except to set four copyright royalty rates. The Tribunal does not grant performing rights society status nor does it deny it. It does not have the jurisdiction. What the Tribunal does is it makes a finding as a predicate to an adjudication of royalty claims whether a claimant is a copyright owner or a performing rights society, but the Tribunal's opinion of the status of a claimant has only one effect—that of determining the burden of going forward with the evidence within a Section 116 royalty distribution proceeding. The Tribunal's opinion has no legal effect upon the music industry.

Indeed, the Tribunal believes the obverse, that ACEMLA has urged upon the Tribunal a regulatory function it does not have, so that, if ACEMLA does obtain a finding that it is a performing rights society for the purpose of a Section 116 proceeding, that finding will be used within the music industry by ACEMLA for purposes the Tribunal did not intend. Already, we note that ACEMLA filed in its written direct case that it received royalties from the Tribunal as a performing rights society. This is untrue. LAMCO, a music publisher, was the recipient of 1982/1983 jukebox royalties, and the Tribunal

admonishes ACEMLA for such lack of candor in its pleadings.

Finally, the Tribunal believes that the categorization between copyright owners and performing rights societies which Congress established has a rational basis, and is therefore constitutional.

For most of the above-mentioned reasons, the Tribunal also concludes that IBC was not a performing rights society in 1985. IBC is essentially a music subpublisher for several Italian publishers abroad. It has a longer history than ACEMLA, and it has 10 or 11 radio station licenses, and some minor licenses for the public performance of music at restaurants, theaters and concert halls. However, it has taken no structural steps to create a performing rights society apart from its functions as a music subpublisher. It has no members or affiliates. It has no distribution system. It made no distributions in 1985. It pays the Italian publishers based upon its contract with them. It does not pay the writer directly, and if the writer does not get paid, the writer's recourse is to the Italian publisher, not IBC.

IBC was described by the Tribunal as a performing rights society in the 1979/1980 jukebox distribution final determination, but this was made upon the representation of IBC without inquiry by the Tribunal. When the Tribunal was instructed by the Court of Appeals that the status of a claimant is a necessary predicate to determining the burden of going forward with the evidence, the Tribunal first took up the status of IBC in the 1982/1983 consolidated jukebox proceeding, and in that proceeding, IBC signed a stipulation that stated that it was a copyright owner, not a performing rights society.

ACEMLA/IBC argue that a signed stipulation does not bind parties in subsequent proceedings, citing *Red Lake Band v. U.S.*, 607 F. 2d 930 (U.S. Ct. of Cl. 1979). A look at the facts underlying *Red Lake Band* shows that *Red Lake Band* does not stand for such a broad proposition. In *Red Lake Band*, a stipulation signed as a co-defendant by Red Lake Band in 1935 as to the value of certain land was deemed not to bind Red Lake Band when it became a plaintiff decades later for the value of the same land. It was found that the stipulation was not necessary to the determination of the 1935 case, and that it was not anticipated at the time of the stipulation that U.S. law would change making it possible for Red Lake Band to sue for an amount greater than the value of the stipulation. Hence, the court was led to a finding that Red Lake Band did

not have the necessary intent for its stipulation to bind it in future proceedings.

Strict application of collateral estoppel, based on IBC's stipulation, would mean that the Tribunal would look only at the years 1984 and 1985 to determine whether any circumstances had changed to indicate that IBC had become a performing rights society. The Tribunal has chosen not to apply collateral estoppel, but to take up an analysis of IBC from its inception. We do note, however, that the stipulation is part of a pattern of inconsistency in which IBC sometimes represents itself as a performing rights society to the industry and to the Tribunal, and sometimes it does not. The Tribunal considers all such self-representations as irrelevant, and has determined that IBC is a music subpublisher, not a performing rights society, based upon the substance of IBC's operations.

Effect of the Tribunal's First Conclusion

The Tribunal has concluded that ACEMLA and IBC were copyright owners in 1985. The next step is to consider the value of the music ACEMLA and IBC control. After Tribunal consideration of ACEMLA and IBC, the Tribunal's task is complete because the three performing rights societies are in agreement.

It was the intent of Congress and it is the policy of the Tribunal to encourage settlements in royalty distribution proceedings. Accordingly, 17 U.S.C. 116(c)(2) states, in part, " * * * for purposes of this subsection any claimants may agree among themselves as to the proportionate division of compulsory licensing fees among them, may lump their claims together and file them jointly or as a single claim, or may designate a common agent to receive payment on their behalf." ACEMLA and IBC have filed a joint claim. Therefore, the Tribunal will consider the sum value of their catalogues only, and will not make any subdetermination of the contribution of ACEMLA's catalogue or IBC's catalogue to the total award. We believe that to do otherwise would tend to negate the settlement between ACEMLA and IBC, and work against Congress' intent and Tribunal policy.

Regarding our consideration of ACEMLA's and IBC's claim, we reiterate our belief expressed in the last proceeding that the status of the claimants, whether copyright owners or performing rights society, does not affect the valuation of their claim. ACEMLA/IBC has argued strenuously that the effect of being the only claimant under the "spotlight" is to place ACEMLA/IBC

at a great disadvantage. We disagree. The Tribunal makes every effort to value the claim in the context of the entire universe of musical works under consideration, regardless of whose burden it is to put forward the evidence. Further, we doubt the very existence of either a procedural or psychological disadvantage of being the only claimant under consideration. We note that in a similar situation in the 1982 cable royalty distribution proceeding where the Devotional Claimants was the only non-settling party and thus had its claim considered alone, the Devotional Claimants had its award increased from 0.35% to 1%. 49 FR 37653.

Findings of Fact

ACEMLA's Proof of Entitlement

In the 1984 jukebox distribution proceeding, the Tribunal awarded ACEMLA, as the assumed name of LAMCO, 0.06% of the jukebox fund. 51 FR 43455. ACEMLA has incorporated by reference the record evidence supporting that award and earlier awards, and a recitation of that evidence is not repeated herein. Supplement to Direct Case of ACEMLA. ACEMLA's entitlement showing in 1985, building upon earlier showings, is as follows:

Demographics. In March, 1985, there were 16.9 million persons of Spanish origin in the United States, representing an increase of 2.3 million persons over the 1980 Census figure of 14.6 million. ACEMLA Ex. 4. According to *Broadcasting Cablecasting Yearbook 1986*, there were 207 Spanish-language radio stations in the United States in 1985, 59 in Texas, 46 in California, and 36 in Puerto Rico. ACEMLA Ex. 5, pp. 1-2.

Additions to ACEMLA catalogue. In November, 1986, ACEMLA entered into an agreement with SPACEM, an association of composers in Puerto Rico, to collect and distribute performing rights royalties for it, retroactive to April 1, 1985. ACEMLA Ex. 1, p. 1. ACEMLA signed up certain additional individual composers in 1985, and in 1986, ACEMLA entered into agreements with six Dominican Republic composers who authorized ACEMLA to collect performing rights royalties for the year 1985. *Id.*, p. 2.

In rebuttal, ASCAP asserted that SPACEM had a pre-existing agreement with ASCAP for 1985. Reb. Test. of Adler, pp. 7-9. Robert L. Ahrold (Ahrold), testifying for BMI, stated that under the ASCAP/SPACEM agreement, U.S. publishers who may not have been members of ASCAP may have acquired rights to individual songs written by

SPACEM writers. Accordingly, BMI publisher affiliates have acquired the rights to over 900 works by approximately 60 SPACEM writers. A/B/S Ex. 33R; Tr. 446-447.

Monitoring of public performances of ACEMLA works. ACEMLA undertook a limited monitoring of three New York City radio stations in 1985 to determine which titles in its repertory were being broadcast. Radio station WADO was monitored on 14 days, WJIT was monitored on 10 days, and WSKQ was monitored on 5 days. In total, 138 different ACEMLA-controlled songs (including 5 based upon ACEMLA's agreement with SPACEM) were played during this limited monitoring. ACEMLA Ex. 6. ACEMLA's monitoring was not conducted on any scientific basis. The recordings were not made continuously, and so do not show the frequency of performance of ACEMLA-claimed songs in relation to other songs. Tr. 343. The three New York stations do not constitute a representative sample of all Spanish-language radio stations. Tr. 344.

Hit Songs Charts. ACEMLA analyzed 19 of 52 weekly *Billboard* Top Latin Album charts published in 1985, and found that 47 songs in its repertory appeared on 32 of the albums listed. This included 13 songs by virtue of the contract with SPACEM. ACEMLA Ex. 7.

Daily newspapers *Noticias El Mundo* and *Vocero*, published in New York City, published lists of the most popular Spanish-language records from time to time in 1985, and 18 ACEMLA-controlled songs were included in these lists. ACEMLA Ex. 8.

A bi-weekly magazine, *Guia Radial Del Show*, published hit songs charts during 1985, based upon information furnished by a Puerto Rican record store, and various ACEMLA-controlled songs appeared regularly on those lists. ACEMLA Ex. 9.

In rebuttal, Robert L. Ahrold, Vice President for Corporate Relations for BMI, testified that popularity on long-playing albums, such as those listed on *Billboard's* Latin Album charts, does not translate to popularity as 45 rpm singles, suitable for jukebox play. Reb. Test. of Ahrold, pp. 5-7. Ahrold worked in 1985 as Vice President for Communications for RCA/Ariola. RCA/Ariola produced 130 Spanish-language albums in 1985. RCA/Ariola produced very few 45 rpm records for either promotional or commercial use. The emphasis was almost entirely on the long-playing format in 1985, and Ahrold believes this practice is true for the Latin music industry in general. *Id.*

Again, in rebuttal, Emilio Garcia, Manager of the International Department for The Harry Fox Agency,

Inc., testified as an expert in the Latin music industry. Reb. Test. of Emilio Garcia. Based upon his experience, Garcia testified that 45 rpm records in the Latin music industry were insignificant in 1985. Virtually the entire run of Spanish-language 45's are pressed for promotional purposes, and sent to radio stations as promotional copies. Consequently, there are almost no Spanish-language 45's for commercial sale and possible play in jukeboxes. *Id.*, p. 5.

Garcia also testified that record store song charts are not a reliable basis for determining play of Spanish-language music on jukeboxes. In Garcia's view, record store song charts are promotional devices, listing not necessarily those songs which are selling, but those songs which a particular store publishing the chart wants to sell. *Id.*, p. 7. Garcia believes that record store charts do not have any significance beyond the immediate community for which they are produced and distributed. *Id.* Garcia believes this is especially true for this proceeding, given the great diversity of musical interests and tastes within the Spanish-speaking communities of the United States. Garcia believes that ACEMLA Ex. 9 demonstrates nothing beyond what the songs the store in question, Music City, may be selling or wanting to sell in Carolina, Puerto Rico. *Id.*, p. 9. Garcia also denies Bernard's assertion that Puerto Rico is a distribution center for Spanish-language 45 rpm records. According to Garcia, there are two pressing plants in Puerto Rico and they press product for small local labels only. They have no accounts from the mainland. *Id.*, p. 10.

Also, in rebuttal, A/B/S asserts that charts relating to Puerto Rico are not relevant to this proceeding, because there were no licensed jukeboxes in Puerto Rico in 1985. A/B/S Ex. 22X.

A/B/S Radio Survey, and Dispute of Title Ownership. As in prior years, A/B/S performed a radio survey of ACEMLA-controlled works. Reb. Test. of Adler; Reb. Test. of Ahrold. In this proceeding, A/B/S performed a survey of the songs listed by ACEMLA in the 1982-1984 proceeding, and the songs listed for the first time in the 1985 proceeding. Reb. Test. of Ahrold, p. 3. Prior to aggregating the survey results for each song, A/B/S deleted from the list 62 songs which A/B/S believed were in the combined repertoires of A/B/S. A/B/S Ex. 24R; Reb. Test. of Adler, p. 11; Reb. Test. of Ahrold, p. 3.

ACEMLA sought and received leave to file rebuttal to show that those 62 songs which A/B/S believes are in the A/B/S catalogues, are, in fact, in

ACEMLA's catalogue. Tr. 447-448; ACEMLA Ex. 25.

In ACEMLA Exhibit 25, ACEMLA offered no statement in regard to 14 of the 62 songs. In regard to "La Revancha," ACEMLA acknowledged that the rights to it had been released back to the author who may have licensed the rights to someone else in 1985. In regard to four other songs, "La Guagua," "La Piragua," "Navidad Negra," and "San Fernando," ACEMLA relied on the personal assurances that these songs are in ACEMLA's catalogue. ACEMLA's claim to another 19 titles is based on its agreement with SPACEM, an agreement A/B/S disputes is valid. ACEMLA Ex. 25.

The Tribunal requested of A/B/S the radio survey results including the 62 contested songs, and excluding the 62 contested songs. Tr. 483. Excluding the 62 contested songs, according to ASCAP's methodology, if ACEMLA had been an ASCAP member in 1985, it would have earned for 396 songs, 2,370 radio credits out of a total of 13,235,103 earned by all ASCAP members, yielding a percentage of 0.01791%. Reb. Test. of Adler, pp. 12-13. Including the 62 contested songs, the percentage is 0.03277%. A/B/S Proposed Findings, par. 110, fn. 35. This compares with a result reached by ASCAP in the 1984 jukebox proceeding of 0.02065%. 1984 Reb. Test. of Adler, pp. 12-15.

BMI conducted a similar radio survey, using the same parameters as ASCAP did in its study. BMI determined that if ACEMLA had been a BMI affiliate in 1985, their musical works would have accounted for 0.001383% of BMI's distribution for all similar U.S. radio performances. Reb. Test. of Ahrold, p. 5. Including the 62 contested songs, the percentage is 0.00453%. A/B/S Proposed Findings, par. 110, fn. 36. This compares with BMI's survey results for 1984 which yielded 0.001850%. 1984 Reb. Test. of Alan Smith, pp. 4-6.

IBC Proofs of Entitlement

IBC received cash awards from the Tribunal of \$1000 and \$800 in the 1979 and 1980 jukebox distribution proceedings, respectively. 47 FR 18406. These are the only proceedings in which IBC litigated its claim and which have precedential value. IBC incorporated by reference the evidence underlying the awards of the 1979 and 1980 proceeding. Supplement to Direct Case of IBC.

IBC has about 25,000 Italian-language songs composed between 1900 and 1972 in its repertory. IBC Ex. 1, p. 1. Mr. Frank Tudisco, owner of IBC, stated that there are thousands of Italian pizza parlors in the United States which play the older Italian songs on jukeboxes. Tr. 296. In

the old pizza parlors, whenever the records are changed in the jukeboxes, according to Tudisco, four or five of the old Italian records stay in the jukeboxes. Tr. 311.

IBC Exhibit 1 included photocopies of a few record jackets from Italian-language 45 rpm records which purport to list other 45 rpm records available for sale. IBC indicated on these record jackets 62 songs which it claims. IBC Ex. 1, Attachment. IBC could offer no underlying documentation to identify the sources and dates of publication of the record jackets. Tr. 304.

In rebuttal, ASCAP performed a radio survey of IBC works. First, ASCAP asserts that 7 of the 62 IBC-claimed songs are actually in the A/B/S repertories. A/B/S Ex. 27R; Reb. Test. of Adler, p. 10. Eliminating those works from its consideration, but including 400 songs which IBC previously provided to ASCAP as representing its most significant songs, ASCAP states that it found that only one IBC-claimed song had any performances in its radio survey in 1985. The credits IBC would have earned for that song would have been 20.854, or 0.00016% of the total radio credits earned by ASCAP works. Reb. Test. of Adler, p. 15.

Conclusions of Law—ACEMLA's and IBC's Entitlements

It is the Tribunal's conclusion that ACEMLA and IBC, collectively, have shown entitlement to 0.12% of the 1985 jukebox royalty fund.

The Tribunal's analysis proceeds from the levels of entitlement previously shown by ACEMLA and IBC. ACEMLA was awarded 0.06% of the 1984 jukebox royalty fund. The last time IBC litigated its award, 1979 and 1980, it was awarded \$1000 and \$800 for those two proceedings, which translates to 0.74% and 0.65% of the 1979 and 1980 funds, respectively. Based upon previously established entitlements only, the collective award for ACEMLA and IBC would be in the range of 0.125% to 0.135%.

It does not appear to the Tribunal that ACEMLA and IBC have proved their entitlement in the 1985 proceeding to the levels previously proved, and a slight downward adjustment to 0.12% is warranted.

Regarding ACEMLA's proofs, there was some indication that perhaps in 1985 ACEMLA had published more of its works, and more of its works were being performed, generally. Agreements which were only entered into during 1982-1984 presumably were in fuller operation in 1985, and 45 rpm records which were pressed in 1982-1985 could have gained greater circulation in 1985 as ACEMLA's

publishing efforts might have begun to pay off. The most persuasive evidence regarding this is the monitoring of three New York stations which shows that ACEMLA's works were beginning to be played over the air in 1985. Higher credit to ACEMLA's contribution to the collective award to ACEMLA and IBC might therefore be justified.

However, certain criticism of ACEMLA's proofs must be noted, and that criticism comes mainly in the lack of nexus between the assertions of ACEMLA and any desired conclusion that ACEMLA may want the Tribunal to reach. The demographic evidence, for example, which ACEMLA has offered in each year's proceedings has no demonstrable nexus to ACEMLA's entitlement. It is presumed that ACEMLA offered evidence of an increase in Spanish-language persons in the United States from 1980 to 1985 to demonstrate a greater audience for its works, but these demographic figures in no way lead the Tribunal to understand what percentage of Spanish-language music in the United States ACEMLA controls. In fact, ACEMLA's other proffered demographic evidence, that there are 207 Spanish-language format radio stations in the United States is damaging to ACEMLA's case, rather than helpful. ACEMLA has obtained only one license from 207 radio stations, and that license is for only \$1500 a year, indicating to us that the station is paying ACEMLA only for a fraction of the music it uses. Clearly, this statistic reveals that the vast majority of Spanish-language music in the United States is not under ACEMLA's control.

The lack of nexus in the rest of ACEMLA's proofs is also evident. Although we have credited the works monitored by ACEMLA on three New York stations, it has not given us a statistically usable measure to relate that evidence to ACEMLA's percentage entitlement.

We are particularly concerned by the credible evidence given by Latin music experts, that generally, in the Latin music industry, 45 rpm records play little or no role. If that were true, then the album charts and the radio play would have little connection to jukebox play. What is key, however, to the testimony of the Latin music experts is that they were speaking only for the general industry practice, and not to ACEMLA's practices in particular. We are not inclined, therefore, to discredit ACEMLA's evidence on that basis. However, we would require in future proceedings that ACEMLA explain to the Tribunal more of its operations—which songs have been recorded on 45

rpm records, how many were released, how have they been distributed, and where.

Regarding the ASCAP and BMI radio surveys, they indicate a general continuity of some radio play of ACEMLA works. Any fluctuation in the actual percentages from 1984 were not considered great enough to change our analysis of ACEMLA's entitlement. We do note that there were a number of disputes regarding the right of ACEMLA to represent several works, and the right of ACEMLA to represent the SPACEM writers. Within the context of the ASCAP and BMI radio surveys, the results of those surveys with or without the 62 contested songs were well within the mathematical range of possible error the Tribunal had previously built into the award to ACEMLA in 1984, so that no resolution of those disputes was necessary. We also believe that we did not need to weigh the effect of SPACEM writers as purported contractors of ACEMLA to conclude this year's entitlement. However, we are disturbed by the number of contested works, and contested contracts. We stated in the 1984 cable royalty distribution final determination that the Tribunal is not the appropriate forum for contract dispute resolution. 52 FR 8411. This proceeding shows clearly the reason for this. ACEMLA asserts that it has signed SPACEM, and ASCAP asserts that SPACEM had a pre-existing agreement with ASCAP. A proper handling of this

issue would take an amount of time equal perhaps to an entire jukebox distribution proceeding, and we do not believe it was intended for the Tribunal to so devote its resources. We urge the parties to settle or stipulate these matters as best they can prior to or during the proceeding, or take the matter to court. In the event that these efforts fail, and that the matter is considered material to the Tribunal's deliberations, the Tribunal may have to assign these works to one claimant or another for the purposes only of a Section 116 proceeding on far less than the best evidence.

Regarding IBC's proofs, the Tribunal has been given almost no evidence from which to derive its conclusions. General statements about the size of the IBC catalogue, its long-time value in Italian neighborhoods, and an undocumented list of 62 songs are not sufficient. The Tribunal needs more hard facts about the nature of IBC's operations, similar to the questions we asked about ACEMLA—how many IBC Italian-language 45 rpm singles have been produced, released, sold, and where.

The value which the Tribunal has given IBC's claim is based almost solely on the previous records of 1979 and 1980. However, we state that this is the last proceeding in which the records of 1979 and 1980 will carry much weight, absent new evidence. IBC must demonstrate anew the marketplace value of its works, and a nexus must be

shown with jukebox play. For example, our own review of the previous records shows a number of movie titles on which IBC relied, and it is not clear to us whether those movie titles were released as 45 rpm singles, and whether they have enduring value. This admonition to maintain an updated record is consistent with our conclusion in regard to NAB in the 1984 cable distribution proceeding, wherein we stated that the marketplace value of NAB's works would have to be updated from the 1979 proceeding. 51 FR 8419-20.

Our last admonition to ACEMLA and IBC is that the pattern of their witnesses to be reluctant to give precise answers, and to engage in "puffery," will result in adverse conclusions drawn by the Tribunal. As we stated last year, it is not our task to sort out a poorly constructed record.

Allocations

Accordingly, the Tribunal awards 0.12% of the 1985 jukebox royalty fund to ACEMLA as the assumed name of Latin American Music Co, Inc., and to Italian Book Corporation, collectively. The remainder of the fund is awarded to ASCAP, BMI and SESAC, Inc., collectively.

J.C. Argetsinger,
Chairman.

Dated: November 30, 1987.

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**Endangered
Species
Act
Regulations**

**Friday
December 4, 1987**

Part V

**Department of the
Interior**

Fish and Wildlife Service

50 CFR Part 17

**Endangered and Threatened Wildlife
and Plants; Proposed Rules**

DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Proposal To Determine *Iris lacustris* (Dwarf Lake Iris) To Be a Threatened Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Service proposes to determine a plant, *Iris lacustris* (dwarf lake iris), to be a threatened species under the authority contained in the Endangered Species Act of 1973, as amended (Act). *Iris lacustris* is found at about 30 sites in Michigan and Wisconsin, as well as several areas in Ontario. Threats to this species include continued loss of habitat and lack of appropriate vegetation management. This proposed rule, if made final, will extend the Act's protection to *Iris lacustris*. The Service seeks further data and comments from the public on this proposed rule.

DATES: Comments from all interested parties must be received by February 2, 1988. Public hearing requests must be received by January 19, 1988.

ADDRESS: Comments and materials concerning this proposal should be sent to the Endangered Species Division, U.S. Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: James M. Engel (see ADDRESSES section) at 612/725-3276 or FTS 725-3276.

SUPPLEMENTARY INFORMATION:

Background

Iris lacustris, a member of the family Iridaceae, has been treated as a variety of *Iris cristata* (Dykes 1913), but is recognized by others as a distinct species (Foster 1937). Taxonomic debate continues (Makhholm 1986). *Iris lacustris* is an herbaceous perennial, a diminutive iris with flat, erect, narrow leaves that sheath each other at the base. Leaves are 3 inches (7.5 centimeter) tall at the onset of flowering in late spring, later reaching 5-6 inches (15 cm). The flowers are 2-2.5 inches (6 cm) long, have three petals and range from pale lilac to dark violet in color. Fruit capsules are about 1 inch (2.5 cm) tall and triangular. *Iris lacustris* is rhizomatous and forms dense colonies under favorable conditions.

Iris lacustris is found in Michigan, Ontario, and Wisconsin. Reports in the literature of this species' occurrence on the shores of Lake Superior have been discounted (Guire and Voss 1963). In Michigan, the species is found at about 60 sites in ten counties on the northern shores of Lakes Michigan and Huron (The Nature Conservancy data files). In Ontario, it is found on Manitoulin Island and the Bruce Peninsula. Makhholm (1986) recorded *Iris lacustris* at 12 scattered colonies on Wisconsin's Door Peninsula. The lakeshore habitat of this species is usually sandy or gravelly and open, although the plant occurs in the partial shade of coniferous trees and in mesic areas at the forest edge. *Iris lacustris* grows in dense colonies on open beach habitat but is scattered in small patches in upper beach habitats, where it is shaded (Makhholm 1986).

Although some colonies of *Iris lacustris* are protected on public land, most of the plants are threatened by habitat destruction and a lack of active management. The rarity of the species and various threats indicate that it is likely to become endangered in the long term. Federal actions involving this iris began with Section 12 of the Endangered Species Act of 1973, which directed the Secretary of the Smithsonian Institution to prepare a report on those plants considered to be endangered, threatened, or extinct. This report, designated as House Document No. 94-51, was presented to Congress on January 9, 1975. On July 1, 1975, the Service published a notice in the *Federal Register* (40 FR 27823) of its acceptance of the report of the Smithsonian Institution as a petition within the context of section 4(c)(2), now section 4(b)(3)(A), of the Act and of its intention thereby to review the status of those plants. *Iris lacustris* was included in the Smithsonian petition as a candidate for threatened status.

On December 15, 1980, the Service published a revised notice of review for native plants in the *Federal Register* (45 FR 82480); *Iris lacustris* was included as a Category-1 species (species for which data in the Service's possession indicate listing is warranted). This iris was still included in Category 1 in the September 27, 1985, revised notice of review of plants (50 FR 39526).

Section 4(b)(3)(B) of the Endangered Species Act, as amended in 1982, requires the Secretary to make findings on certain pending petitions within 12 months of their receipt. Section 2(b)(1) of the 1982 amendments further requires that all petitions pending on October 13, 1982, be treated as having been newly submitted on that date. This was the case for *Iris lacustris* because the 1975

Smithsonian report had been accepted as a petition. On October 13, 1983; October 12, 1984; October 11, 1985; October 10, 1986; and October 14, 1987, the Service found that the petitioned listing of these species was warranted, but that listing this species was precluded due to other higher priority listing actions. Publication of the present proposal constitutes the final 1-year finding required for these three species which are now among the highest priority species for listing.

Summary of Factors Affecting the Species

Section 4(a)(1) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and regulations (50 CFR Part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal lists. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1). These factors and their application to *Iris lacustris* Nuttall (dwarf lake iris) are as follows:

A. *The present or threatened destruction, modification, or curtailment of its habitat or range.* *Iris lacustris* formerly was more widely distributed than it is today (Guire and Voss 1963, Crispin 1981, Makhholm 1986). Major habitat areas in Michigan have been significantly altered by private development to the extent that they cannot support *Iris lacustris* populations (Crispin 1981). Development of private shore areas continues and is increasing. Private residential development is the greatest threat to *Iris lacustris*. In Wisconsin, Alverson (1981) identified home and cottage construction, road widening, chemical spraying and salting, and off-road vehicle use as current threats to the species' habitat.

B. *Overutilization for commercial, sporting, scientific or educational purposes.* Not known to be a threat. However, the species has attractive flowers and so has commercial potential.

C. *Disease or predation.* Not known to be a threatening factor.

D. *The inadequacy of existing regulatory mechanisms.* This species is listed as threatened by the States of Michigan and Wisconsin. Wisconsin regulations prohibit any person from removing or transporting any endangered or threatened wild plant away from its native habitat on public property, or from property he or she does not own or control, except in the course of forestry or agricultural practices or in the construction and

maintenance of a utility facility. The Michigan Endangered Species Act requires developers to determine threatened species involvement in proposed projects. Although *Iris lacustris* is offered various forms of protection under these State laws, monitoring and enforcement are difficult due to limited personnel. The Endangered Species Act offers possibilities for protection of this taxon through section 6 by cooperation between the States and the Service and through section 7 (Interagency Cooperation) requirements. The Endangered Species Act would provide additional protection for *Iris lacustris* through section 9 and the recovery process.

E. *Other natural or manmade factors affecting its continued existence.* *Iris lacustris* colonies require management to maintain required open habitat. Successional processes have altered some habitat beyond the tolerance limit for the species.

The Service has carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this species in determining to propose this rule. Based on this evaluation, the preferred action is to list *Iris lacustris* as threatened. Threatened status is proposed due to the species' restricted range and the threats facing it and its habitat. Since the iris is not in any immediate threat of extinction, largely because of its scattered distribution, the Service is not proposing it for endangered status. Critical habitat is not being proposed for reasons discussed in the following section.

Critical Habitat

Section 4(a)(3) of the Act, as amended, requires that to the maximum extent prudent and determinable, the Secretary designate any habitat of a species which is considered to be critical habitat at the time the species is determined to be endangered or threatened. The Service finds that designation of critical habitat is not prudent for a *Iris lacustris* at this time. Publishing a detailed description and map of this species' habitat might stimulate public interest and make this species more vulnerable to taking by collectors (see factor "B" in the "Summary of Factors Affecting the Species"). Also, collecting of listed plants is not prohibited by the Endangered Species Act, except from land under Federal jurisdiction. The only site where this plant is found on Federal land is near a U.S. Coast Guard lighthouse. No offsetting benefit would be derived from designating critical habitat. Therefore, it would not be

prudent or beneficial to determine critical habitat for *Iris lacustris* at this time.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Endangered Species Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in conservation actions by Federal, State, and private agencies, groups, and individuals. The Endangered Species Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. Such actions are initiated by the Service following the listing, or even prior to the listing, circumstances permitting. Recovery actions that may prove beneficial to *Iris lacustris* include habitat management to reduce shade and competition of other plants and transplanting to previously occupied sites. The protection required of Federal agencies and the prohibitions against taking are discussed, in part, below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR Part 402. Section 7(a)(4) requires Federal agencies to confer informally with the Service on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species, the responsible Federal agency must enter into formal consultation with the Service. No Federal involvement is anticipated for *Iris lacustris* at this time.

The Act and its implementing regulations found at 50 CFR 17.71 and 17.72 set forth a series of general trade prohibitions and exceptions that apply to all threatened plant species. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export any threatened plant, transport it in interstate or foreign commerce in the

course of a commercial activity, sell it or offer it for sale in interstate or foreign commerce, or remove it from areas under Federal jurisdiction and reduce it to possession. Seeds from cultivated specimens of threatened plant species are exempt from these prohibitions provided that a statement of "cultivated origin" appears on their containers. Certain exceptions can apply to agents of the Service and State conservation agencies. The Act and 50 CFR 17.72 also provide for the issuance of permits to carry out otherwise prohibited activities involving threatened species under certain circumstances. With respect to *Iris lacustris*, it is anticipated that few trade permits would ever be sought or issued since the species is not common in cultivation or in the wild. Requests for copies of the regulations on plants and inquiries regarding them may be addressed to the Federal Wildlife Permit Office, U.S. Fish and Wildlife Service, Washington, DC 20240 (703/235-1903).

Public Comments Solicited

The Service intends that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, any comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning any aspect of this proposed rule are hereby solicited. Comments particularly are sought concerning:

(1) Biological, commercial trade, or other relevant data concerning any threat (or lack thereof) to *Iris lacustris*;

(2) The location of any additional populations of *Iris lacustris* and the reasons why any habitat should or should not be determined to be critical habitat as provided by section 4 of the Act;

(3) Additional information concerning the range and distribution of this species; and

(4) Current or planned activities in the subject area and their possible impacts on *Iris lacustris*.

Final promulgation of the regulation on *Iris lacustris* will take into consideration the comments and any additional information received by the Service, and such communications may lead to adoption of a final regulation that differs from this proposal.

The Endangered Species Act provides for a public hearing on this proposal, if one is requested. Requests must be filed within 45 days of the date of the proposal. Such requests must be made in writing and addressed to the Endangered Species Division (see ADDRESSES section).

National Environmental Policy Act

The Fish and Wildlife Service has determined that an Environmental Assessment, as defined under the Authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. A notice outlining the Service's reasons for this determination was published in the *Federal Register* on October 25, 1983 (48 FR 49244).

References Cited

- Alverson, W.S. 1981. Status report on *Iris lacustris*. Wisconsin Dept. Nat. Res. Unpubl. rep. 13 pp.
Crispin, S.R. 1981. *Iris lacustris* in Michigan. Unpubl. rep. 6 pp.
Dykes, W.R. 1913. The genus *Iris*. Univ. Press, Cambridge. 245 pp.

Foster, R.C. 1937. A cyto-taxonomic study of the North American species of *Iris*. Contr. Gray Herb. No. 69. 21 pp.

Guire, K.E., and E.G. Voss. 1963. Distribution of distinctive shoreline plants in the Great Lakes Region. Michigan Bot. 2:99-114.
Makholm, M.M. 1986. Ecology and management of *Iris lacustris* in Wisconsin. M.S. thesis, Univ. Wisconsin. 123 pp.

Author

The primary author of this proposed rule is John G. Sidle (see ADDRESSES section).

List of Subjects in 50 CFR Part 17

Endangered and threatened wildlife, Fish, Marine mammals, Plants (agriculture).

Proposed Regulation Promulgation

Accordingly, it is hereby proposed to amend Part 17, Subchapter B of Chapter

I, Title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for Part 17 continues to read as follows:

Authority: Pub. L. 93-205, 87 Stat. 884; Pub. L. 94-359, 90 Stat. 911; Pub. L. 95-632, 92 Stat. 3751; Pub. L. 96-159, 93 Stat. 1225; Pub. L. 97-304, 96 Stat. 1411 (16 U.S.C. 1531 *et seq.*); Pub. L. 99-625, 100 Stat. 3500 (1986), unless otherwise noted.

2. It is proposed to amend § 17.12(h) by adding the family Iridaceae in alphabetical order, to the List of Endangered and Threatened Plants:

§ 17.12 Endangered and threatened plants.

* * * * *
(h) * * *

Scientific name	Species	Common name	Historic range	Status	When listed	Critical habitat	Special rules
Iridaceae—Iris family: <i>Iris lacustris</i>		Dwarf lake iris	U.S.A. (MI, WI), Canada (ON)	T		NA	NA

Dated: October 22, 1987.

Susan Recce,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 87-27915 Filed 12-3-87; 8:45 am]

BILLING CODE 4310-55-M

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Proposed Threatened Status for *Oxytropis campestris* var. *chartacea*

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Service proposes to determine threatened status for *Oxytropis campestris* var. *chartacea* (Fassett's locoweed). This plant is known from six sites in Portage and Waushara Counties, Wisconsin. Threats include human disturbance and grazing. This proposal, if made final, will implement the protection of the Endangered Species Act of 1973, as amended, for *Oxytropis campestris* var. *chartacea*. The Service seeks data and comments from the public.

DATES: Comments must be received by February 2, 1988. Public hearing requests must be received by January 19, 1988.

ADDRESSES: Comments and materials concerning this proposal should be sent to the Endangered Species Division, U.S.

Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: James M. Engel at the above address (612/725-3276 or FTS:725-3276).

SUPPLEMENTARY INFORMATION:

Background

Oxytropis campestris var. *chartacea*, a member of the pea family, Fabaceae, was first described as a distinct species, *Oxytropis chartacea* (Fassett 1936). This herbaceous perennial has many leaves clustered in a rosette at the base of the stem. Leaves are pinnately compound, 2 to 8 inches (5 to 20 centimeters) long, with about 15 pairs of small, pointed leaflets (Alverson 1982).

Barneby (1952) considered the taxon a variety of *Oxytropis campestris*. Although it is very similar to var. *johannensis*, the pod of var. *chartacea* is shorter than that of var. *johannensis*, and the "vesture of the whole plant more copious and looser, the stipules permanently pilose," than var. *johannensis* (Barneby 1952). *Oxytropis campestris* var. *chartacea* produces attractive rose-purple flowers from mid-May through mid-June. Fruits develop as individual pods from each flower.

Oxytropis campestris var. *chartacea* is known from six sites (about 4,500

individual plants) in Portage and Waushara Counties, central Wisconsin. Attempts to locate additional populations have been unsuccessful. The species occurs on open sandy lake shores in pure stands, and often in association with *Carex* spp., *Juncus* spp., and *Eleocharis* spp. Lake level fluctuations maintain the species' required open habitat.

Oxytropis campestris var. *chartacea* was among those species covered by a report on endangered, threatened, and extinct plants, which was prepared by the Secretary of the Smithsonian Institution in accordance with Section 12 of the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*). This report, designated as House Document No. 94-51, was presented to Congress on January 9, 1975. In the *Federal Register* of July 1, 1975 (40 FR 27823-27924), the Service issued a notice of its acceptance of this report as a petition within the context of section 4(c)(2) of the Act (petition acceptance provisions are now contained in Section 4(b)(3)(A) of the Act, as amended), and of its intention to review the status of the plant taxa named therein. In the *Federal Register* of June 16, 1976 (41 FR 24523-24572), the Service issued a proposed rule to determine endangered status for approximately 1,700 vascular plant species, including *O. c.* var. *chartacea*. General comments received on the proposal were summarized in the

Federal Register of April 26, 1978 (43 FR 17909-17916).

The Endangered Species Act Amendments of 1978 required the withdrawal of all proposed rules over 2 years old, though a 1-year grace period was allowed to proposals then already over 2 years old. Accordingly, in the Federal Register of December 10, 1979 (44 FR 70796-70797), the Service issued a notice withdrawing that portion of the proposal of June 16, 1976, that had expired, along with four other proposals that had expired. In the Federal Register of September 27, 1985 (50 FR 39526-239527), the Service issued a revised notice of review. *O. c. var. chartacea* was placed in Category 1 of that notice, meaning that the Service had substantial information supporting the appropriateness of proposing endangered or threatened status.

The Endangered Species Act Amendments of 1982 required that petitions, such as that comprised by the Smithsonian report, which were still pending as of October 13, 1982, be treated as having been received on that date. Section 4(b)(3) of the Act, as amended, requires that, within 12 months of the receipt of such a petition, a finding be made as to whether the requested action is warranted, not warranted, or warranted but precluded by other activity involving additions to or removals from the Federal Lists of Endangered and Threatened Wildlife and Plants. Therefore, on October 13, 1983, the Service made the finding that determination of endangered status for *O. c. var. chartacea* was warranted but precluded by other listing activity. In the case of such a finding, the petition is recycled and another finding becomes due within 12 months. On October 12, 1984; October 11, 1985; October 10, 1986; and October 14, 1987; additional findings of warranted but precluded were made with respect to the listing of *O. c. var. chartacea*. This proposal constitutes the final 1-year finding required for a petition to list a species as endangered or threatened.

Summary of Factors Affecting the Species

Section 4(a)(1) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and regulations (50 CFR Part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal Lists. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in Section 4(a)(1). These factors and their application to *Oxytropis campestris* var.

chartacea (Fassett) Barneby (Fassett's locoweed) are as follows:

A. *The present or threatened destruction, modification, or curtailment of its habitat or range.* This species occurs wholly on privately-owned land, residential lots, and lake front lots, and at a summer camp. Human use of sandy shorelines has extirpated the plant from several historic sites in Bayfield and Waushara Counties (Alverson 1982). At current sites, plants occur adjacent to areas not used by humans for recreational or other purposes. Although moderate human use of shoreline appears to be compatible with the species' survival, increasing shoreline developments would jeopardize the species.

B. *Overutilization for commercial, recreational, scientific, or educational purposes.* Due to the limited distribution and small population size of *Oxytropis campestris* var. *chartacea*, indiscriminate collecting of any nature could have serious effects.

C. *Disease or predation.* Several of the sites at which *O. c. var. chartacea* formerly occurred have been heavily grazed by domestic livestock for many years. Circumstantial evidence suggests that such grazing eliminated the plant from these sites. Grazing is a potential threat to populations that still survive (Alverson 1982).

D. *The inadequacy of existing regulatory mechanisms.* *Oxytropis campestris* var. *chartacea* is officially listed as threatened in Wisconsin. However, such classification is of little practical benefit, since the species occurs entirely on private land. The Federal Endangered Species Act would provide the basis for substantial additional conservation measures, such as habitat acquisition, land use agreements, and development of a recovery plan.

E. *Other natural or manmade factors affecting its continued existence.* *Oxytropis campestris* var. *chartacea* is vulnerable because of its restricted range and low numbers. A substantial disturbance could reduce a population to the point that long-term genetic viability would be lost, resulting in extinction.

The Service has carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this species in determining to propose this rule. Based on this evaluation, the preferred action is to list *Oxytropis campestris* var. *chartacea* as threatened. Such status is proposed due to the species' restricted range and the multiplicity of problems facing it and its

habitat. It does not, however, appear to be in immediate danger of extinction. Critical habitat is not being proposed for reasons discussed in the following section.

Critical Habitat

Section 4(a)(3) of the Act, as amended, requires that to the maximum extent prudent and determinable, the Secretary designate any habitat of a species which is considered to be critical habitat at the time the species is determined to be endangered or threatened. The Service finds that designation of critical habitat is not prudent for *Oxytropis campestris* var. *chartacea* at this time. Publishing a detailed description and map of this species' habitat might stimulate public interest and make this species more vulnerable to taking by collectors (see factor "B" in the "Summary of Factors Affecting the Species"). No net benefit would be derived from designating critical habitat, and so it would not be prudent to determine critical habitat for *Oxytropis campestris* var. *chartacea* at this time.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Endangered Species Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in conservation actions by Federal, State, and private agencies, groups, and individuals. The Endangered Species Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. Such actions are initiated by the Service following listing, or even prior to listing, circumstances permitting. Recovery actions that may be of benefit to *O. c. var. chartacea* include protection from excessive grazing and pedestrian traffic, and reintroduction on previously occupied sites. The protection required of Federal agencies and the prohibitions against taking are discussed, in part, below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR Part 402. Section 7(a)(4) requires Federal agencies to confer informally with the Service on any action that is likely to

jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species, the responsible Federal agency must enter into formal consultation with the Service. No Federal involvement is anticipated with *Oxytropis campestris* var. *chartacea* at this time.

Section 9 of the Act, and implementing regulations found at 50 CFR 17.71 and 17.72 set forth a series of general trade prohibitions and exceptions that apply to all threatened plants. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export any threatened plant, transport it in interstate or foreign commerce in the course of a commercial activity, sell or offer it for sale in interstate or foreign commerce, or remove it from areas under Federal jurisdiction and reduce it to possession. Seeds from cultivated specimens of threatened plant species are exempt from these prohibitions provided that a statement of "cultivated origin" appears on their containers. Certain exceptions can apply to agents of the Service and State conservation agencies. The Act and 50 CFR 17.72 also provide for the issuance of permits to carry out otherwise prohibited activities involving threatened species under certain circumstances. With respect to *O. c.* var. *chartacea*, it is anticipated that few trade permits would ever be sought or issued since the species is not common in cultivation or in the wild. Requests for copies of the regulations on plants and inquiries regarding them may be addressed to the Federal Wildlife Permit Office, U.S. Fish and Wildlife Service, Washington, DC 20240 (703/235-1903).

Public Comments Solicited

The Service intends that any final rule adopted will be accurate and as effective as possible in the conservation of endangered or threatened species. Therefore, any comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning any aspect of this proposed rule are hereby solicited. Comments particularly are sought concerning:

(1) Biological, commercial trade, or other relevant data concerning any threat (or lack thereof) to *Oxytropis campestris* var. *chartacea*;

(2) The location of any additional populations of *Oxytropis campestris* var. *chartacea* and the reasons why any habitat should or should not be determined to be critical habitat as provided by Section 4 of the Act;

(3) Additional information concerning the range and distribution of this species; and

(4) Current or planned activities in the subject area and their possible impacts on *Oxytropis campestris* var. *chartacea*.

Final promulgation of the regulation on *Oxytropis campestris* var. *chartacea* will take into consideration the comments and any additional information received by the Service, and such communications may lead to adoption of a final regulation that differs from this proposal.

The Endangered Species Act provides for a public hearing on this proposal, if requested. Requests must be filed within 45 days of the date of the proposal. Such requests must be made in writing and addressed to the Endangered Species Division (see ADDRESSES section.)

National Environmental Policy Act

The Fish and Wildlife Service has determined that an Environmental Assessment, as defined by the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to Section

4(a) of the Endangered Species Act of 1973, as amended. A notice outlining the Service's reasons for this determination was published in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

- Alverson, W.S. 1982. Status report on *Oxytropis campestris* L. var. *chartacea* (Fassett) Barneby. Unpubl. rept., 15 pp.
Barneby, R.C. 1952. A revision of the North American species of *Oxytropis* DC. Proc. California Acad. Sci. 17:177-312.
Fassett, N.C. 1936. Notes from the herbarium of the University of Wisconsin, 13. Rhodora 38:77-100.

Author

The primary author of this proposed rule is John G. Sidle, U.S. Fish and Wildlife Service, 1500 Capitol Avenue, Bismarck, North Dakota, 58501.

List of Subjects in 50 CFR Part 17

Endangered and threatened wildlife, Fish, Marine mammals, Plants (agriculture).

Proposed Regulation Promulgation

Accordingly, it is hereby proposed to amend Part 17, Subchapter B of Chapter I, Title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for Part 17 continues to read as follows:

Authority: Pub. L. 93-205, 87 Stat. 884; Pub. L. 94-359, 90 Stat. 911; Pub. L. 95-632, 92 Stat. 3751; Pub. L. 96-159, 93 Stat. 1225; Pub. L. 97-304, 96 Stat. 1411 (16 U.S.C. 1531 *et seq.*); Pub. L. 99-625, 100 Stat. 3500 (1986), unless otherwise noted.

2. It is proposed to amend § 17.12(h) by adding the following, in alphabetical order under Fabaceae, to the List of Endangered and Threatened Plants:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Status	When listed	Critical habitat	Special rules
Scientific name	Common name					
Fabaceae—Pea family:						
<i>Oxytropis campestris</i> var. <i>chartacea</i>	Fassett's locoweed	U.S.A. (WI)	T		NA	NA

Dated: October 22, 1987.

Susan Reece,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 87-27916 Filed 12-3-87; 8:45 am]

BILLING CODE 4310-55-M

Exhibition
Notice
Determination
Imported
Culturally Significant
Objects

Friday
December 4, 1987

Part VI

**United States
Information Agency**

**Culturally Significant Objects Imported
for Exhibition; Determination; Notice**

**UNITED STATES INFORMATION
AGENCY****Culturally Significant Objects Imported
for Exhibition; Determination**

Notice is hereby given of the following determination: Pursuant to the authority vested in me by the act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978 (43 FR 13359, March 29, 1978), and Delegation Order No. 85-5 of June 27,

1985 (50 FR 27393, July 2, 1985), I hereby determine that two paintings entitled "Above the Town" and "St Sebastian", imported from abroad for the temporary exhibition without profit within the United States are of cultural significance. These objects are imported pursuant to a loan agreement between the National Gallery of Art and the Soviet Union. I also determine that the temporary exhibition or display of these paintings at the National Gallery of Art

in Washington, DC, beginning on or about December 6, 1987, to on or about February 15, 1988, is in the national interest.

Public notice of this determination is ordered to be published in the **Federal Register**.

C. Normand Poirier,
Acting General Counsel.

Date: December 3, 1987.

[FR Doc. 87-28084 Filed 12-3-87; 11:37 am]

BILLING CODE 8230-01-M

FRIDAY
DECEMBER 4, 1987

Friday
December 4, 1987

Part VII

**International
Development
Cooperation Agency**

Agency for International Development

**Housing Guaranty Program; Investment
Opportunities; Notice**

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Agency for International Development

Housing Guaranty Program; Investment Opportunities

The Agency for International Development (A.I.D.) has authorized the guaranty of up to 30 Million Dollars (\$30,000,000) loans for the Government of Jamaica as part of A.I.D.'s development assistance program. The proceeds will be used to finance shelter projects for low income families in Jamaica. Two or three borrowings are anticipated over a two year period. In the first stage, the Government of Jamaica has authorized A.I.D. to request proposals from eligible investors for an amount to be borrowed of up to \$20 Million in two scenarios. The name and address of the representatives of the Borrower to be contacted by interested U.S. lenders or investment bankers, the amount of the loan and project number are indicated below:

Government of Jamaica

Project: 532-HG-012—\$12,000,000 or \$20,000,000

1. Ministry of Finance and Planning,
30 National Heroes Circle, P.O. Box 512
Kingston 4, Jamaica, Telex: 2447
Finance.

Attention:

(1) Harry Milner, Financial Secretary,
Telephone: 809/922-3388, 809/922-8601

or

(2) Audley Sailsman, Telephone: 809/922-8784.

2. Caribbean Housing Finance
Corporation, 56 Duke Street, P.O. Box
701, Kingston, Jamaica.

Attention: Sonia Jackson, Acting
General Manager, Telephone: 809/922-2893, 809/922-9011, 809/922-8330.

Expressions of investors interest only are requested under the two scenarios. The first scenario would be a 12 Million Dollar single disbursement loan (early

March 1988 disbursement), while the second scenario would be a two disbursement \$20 Million loan (first disbursement March 1988 with a second disbursement six months later). Investors should contact the Borrower as soon as possible during the week of December 7, 1987 and indicate their interest in providing financing for the Housing Guaranty Program. Following discussions with interested investors, the Borrower will come to New York to finalize the negotiations with investors and to inform the investors of the procedures to be followed in the auction which will occur while the Borrower is in New York.

Deadline for receipt of expressions of interest in Jamaica is December 11, 1987.

Informational expressions of interest should be sent to:

Agency for International Development,
Michael G. Kitay or, Herbert T.
McDevitt, PRE/H, Room 3208 N.S.,
Washington, DC 20523, Telex No.:
892703 AID WSA, Telefax No. 202/
647-1805 (preferred communication)

Ms. Sara Frankel, Assistant Director/
Caribbean, RHUDO/Kingston,
USAID/Kingston, American Embassy,
Washington, DC 20520-3210,
Telephone: (809) 929-8572, 929-3125.

For your information the Borrower is currently considering the following terms:

1. *Maturity:* Up to 30 years
2. *Interest rate:* Option of either fixed or variable, or variable with borrowers right to convert to fixed rate.
3. *Grace Period on Principal:* Ten years with repayment amortizing gradually over the remaining life of the loan.
4. *Prepayment:* Expressions should include the possibility of partial or total prepayment of the loan by the Borrower, if pricing is not materially affected.
5. *Notes:* Preference to limit number of noteholders.
6. *Fees:* Payable at closing from proceeds of loan.
Selection of investment bankers and/or lenders and the terms of the loan are

initially subject to the individual discretion of the Borrower and thereafter subject to approval by A.I.D. The lender and A.I.D. shall enter into a Contract of Guaranty, covering the loan. Disbursements under the loan will be subject to certain conditions required of the Borrower by A.I.D. as set forth in agreements between A.I.D. and the Borrower.

The full repayment of the loan will be guaranteed by A.I.D. The A.I.D. guaranty will be backed by the full faith and credit of the United States of America and will be issued pursuant to authority in section 222 of the Foreign Assistance Act of 1961, as amended (the "Act").

Lenders eligible to receive an A.I.D. guaranty are those specified in section 238(c) of the Act. They are: (1) U.S. citizens; (2) domestic U.S. corporations, partnerships, or associations, substantially beneficially owned by U.S. citizens; (3) foreign corporations whose share capital is at least 95 percent owned by U.S. citizens' and, (4) foreign partnerships or associations wholly owned by U.S. citizens.

To be eligible for an A.I.D. guaranty, the loan must be repayable in full no later than the thirtieth anniversary of the disbursement of the principal amount thereof and the interest rates may be no higher than the maximum rate established from time to time by A.I.D.

Information as to the eligibility of investors and other aspects of the A.I.D. housing guaranty program can be obtained from: Peter M. Kimm, Director, Office of Housing and Urban Programs, Agency for International Development, Room 6212 N.S., Washington, DC 20523, Telephone: 202/647-9082.

Mario Pita,

Deputy Director, Office of Housing and Urban Programs.

Date: December 3, 1987.

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S.J. Res. 98/Pub. L. 100-176

To designate the week of November 29, 1987, through December 5, 1987, as "National Home Health Care Week." (Nov. 30, 1987; 101 Stat. 985; 1 page— Price: \$1.00)

S. 1158/Pub. L. 100-177

Public Health Service Amendments of 1987. (Dec. 1, 1987; 101 Stat. 986; 23 pages) Price: \$1.00